

REGISTRATION

2517-142

ISB'S Front-end PRIA Completeness Screen

Draft 3; 10/25/07

EPA Receipt Date: AUG 11 2010		EPA Reg. Number: <i>2517-PUE</i>		
	Check List Item	Yes	No	N/A
1	Has the PRIA Fee been Paid ; is a copy of the check or Pay.gov receipt included in the Submission Package? <i>(FW)</i>	X		
2	Is an Application Form (EPA Form 8570-1) Included in the Submission Package, is it completely filled out and signed including package type?	X		
3	Is a Confidential Statement of Formula (EPA Form 8570-29) Included in the Submission Package, is it completely filled out and signed (boxes 1-21)?	X		
4	Is a Formulator's Exemption Statement (EPA Form 8570-27) Included in the Submission Package?	X		
5	Is a Certification with Respect to Citation of Data (EPA Form 8570-34) Included in the Submission Package?	X		
6	Is a Data Matrix (EPA Form 8570-35) Included in the Submission Package?	X		
7	Is a Label Included in the Submission Package?	X		
8	Are Data Included in the Submission Package?	X		
9	Is the Submission an Amendment?			

Material to be added to an e-Jacket or Jacket

Reg. No. 2517-142 (RUE)

Description: New Registration label + CSFs (2)

1. ☒ Placement within the e-Jacket/Jacket
 - ☒ Default: (chronological, top = newest)
 - ☐ File Location: (PDF page number)

2. ☒ Send to Data Extraction contractors this material:
 - ☒ Newly stamped accepted label
 - ☐ Notification
 - ☒ New CSF Basic + Alternate, In Envelope
 - ☐ Other: _____

Attach this coversheet to the top of the material or jacket. It must be well-organized and clipped together – NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer's Name: **Rosanna Louie-Juzwiak**

Phone: 308-0037

Division: RD

Date: 28 MAR 2011

REGISTRATION JACKET INTRA-TRANSFER REQUEST

(PLEASE FILL OUT FORM COMPLETELY)

Transfer File To: Richard Gebken

Phone: _____

Reason For Transfer:

- ☐ RSB CHEMISTRY REVIEW
- ☐ CODING (Macfadden)
- ☐ ACTION COMPLETED
- ☐ PRECAUTIONARY LABEL REVIEW
- ☐ WITHDRAW PENDING APPLICATION
- ☐ OTHER _____

TRANSFERRED FROM: Senedu Alemu (Macfadden)

Phone: 305-6178

DATE REQUEST: _____

PM TEAM: _____
(If Applicable)

REGISTRATION NUMBER (S) OF JACKET (S) TO BE TRANSFERRED
(PLEASE INDICATE VOLUME NUMBER IF APPLICABLE)

REGISTRATION #	COMMENTS	LOCATION	OTHER INFORMATION
<u>2517 - 142</u>	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

SPECIAL COMMENTS: _____

FOR FILE ROOM STAFF USE

NOTIFY REQUESTOR: _____

DATE

TIME

INITIALS

PPIS Deficiency Notice

PM NUMBER: 10

REGISTRATION NUMBER: 2517 - 142


Transferred from: Senedu Alemu (Macfadden) Date Processed: 3/29/2011

This jacket has been found to be deficient according to established EPA data processing guidelines for the following reasons:

1. Current accepted label dated ____/____/____
____ is missing from the jacket. ____ is missing acceptance stamp.
____ Acceptance stamp is missing date and/or registration number.
____ Is missing the following information: _____
2. Acceptance letter dated ____/____/____ and associated label are inconsistent concerning: ____ Acceptance date. ____ Product name. ____ Registration number.
3. Comments letter associated with label dated ____/____/____ is missing from the jacket.
4. Accepted (Basic / Alternate) CSF dated ____/____/____
____ Is missing from the jacket. ____ Is misfiled or has wrong registration number.
____ Sole active ingredient source product _____ - _____ has been cancelled.
5. ☒ Active and inert chemical percentages do not equal 100%.
6. ____ Other information missing / inconsistent within the jacket. See below for details.

Kindly review and return to contractor for processing

Thank you.

	<p align="center">U.S. ENVIRONMENTAL PROTECTION AGENCY</p> <p align="center">Office of Pesticide Programs Registration Division (7504P) 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460</p>	<p>EPA Registration No.</p> <p align="center">2517-142</p>	<p>Date of Issuance:</p> <p align="center">MAR 23 2011</p>
<p align="center">NOTICE OF PESTICIDE:</p> <p align="center"> <input checked="" type="checkbox"/> Registration <input type="checkbox"/> Reregistration </p> <p align="center">(under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)</p>		<p>Term of Issuance:</p> <p>Conditional Registration Time-limited: see conditions below</p> <hr/> <p>Name of Pesticide Product:</p> <p>Sergeant's Fipronil + Cyphenothrin + Methoprene Squeeze-on for Dogs</p>	
<p>Name and Address of Registrant (include ZIP Code):</p> <p>Sergeant's Pet Care Products, Inc. c/o Exponent, Inc. 2625 South 158th Plaza Omaha, NE 68130</p>			
<p>Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.</p>			
<p>On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.</p> <p>Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.</p> <p>This product is conditionally registered in accordance with FIFRA §3(c)(7)(a) provided that:</p> <ol style="list-style-type: none"> 1. This registration is time-limited and expires two years from the date this product is first released for shipment. <p>You must provide the Agency with a projected release for shipment date within 30 days of the date of this Notice of Registration. The Agency will calculate the expiration date based on the projected release for shipment date until an actual release for shipment date is provided in writing.</p> <ol style="list-style-type: none"> 2. Consider limiting the formulations of each product to one basic confidential statement of formula. The Agency may require this in the future. It is possible that no additional alternate formulations or minor formulation amendments will be approved for this product in the future. 3. As a condition of registration for this product, within one year from the date of this registration, you must submit the results of Storage Stability and Corrosion Characteristics studies, corresponding to OCSPP Guidelines 830.6317 and 830.6320, respectively, including interim reports made at 0, 3, 6, 9, and 12 month intervals. 			

4. The approval of this registration is contingent on the Agency's review to determine that the study to fulfill OCSP Guideline 830.1800 - Enforcement Analytical Method, is acceptable to support the registration.
5. Within one year of the date on this Notice of Registration, and prior to formulating this product, you must provide the Agency the following:
 - a. The registration number and establishment number of the manufacturing or technical product(s) from which the active ingredient is derived.
 - b. The name and address of the entity from which the manufacturing product(s) was obtained; and
 - c. A copy of the bill of sale for this manufacturing product(s).
6. Within 30 days from the date of this registration, in accordance with FIFRA §3(c)(1)(F) and 3(c)(2)(B), you must submit a copy of all offers to pay compensation and evidence of their delivery, used to support the data required for this product.
7. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product for the quarter that begins on April 1, 2011. The quarterly reports are due two months after each quarter ends.

Please flag any Confidential Business Information as such. Enhanced incident reporting should be submitted to the Product Manager. Quarterly sales information should be submitted to the Registration Division (7504P), to the Product Manager's attention.

The following is a list of information that must be included in the quarterly reports for each incident:

EPA Registration Number

Product name (brand name)

Lot #

Where purchased: internet, store, veterinarian

Active Ingredient(s)

Weight range for product

Date on which incident occurred. (mm/dd/yyyy)

State in which the incident occurred. (standard 2 letter abbreviation)

Registrant case #

Species: dog, cat, other (specify)

Breed: (as reported by pet owner)

Age: months or years

Sex: M, F, or neutered

Weight: pounds

Primary Route of Exposure: dermal, oral, other animal, inhalation, other

Body System: neurological, dermatological, GI, respiratory, ocular, other

Major signs noted with separate column for each sign, using standard terminology

Time to Onset: (hours, days)

Treated by veterinarian: yes or no

First time product used: yes or no

Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)

Any known precondition

EPA Severity Code: death, major, moderate, minor

Outcome: died, recovered, still treated, unknown

8. Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:
 - All incidents should be reported including all minor dermal and ocular irritation reports.
 - Summary table for dogs showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.
 - A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
 - Summary table for dogs and table for cats showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
 - A summary table for dogs showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
 - A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label.
 - A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range.
 - Table showing number of incidents for each dog breed.
 - Table showing number of incidents in dogs for each clinical sign.
 - Table showing number of incidents in dogs for each organ system.
 - Report aggregate incidents, but do not combine moderate and minor incidents.
9. You must submit and/or cite all data required for registration of your product under FIFRA §3(c)(5) when the Agency requires all registrants of similar products to submit such data, and submit acceptable responses required for reregistration of your product under FIFRA §4.

All labeling comments below are in reference to the proposed master label, dated March 4, 2011. These comments apply to all submitted draft labeling, including the master label, the color mock-up labels, and the proposed text and graphics for the stickers and magnet:

10. Throughout the entire label, add "starts killing" so that the claims read as follows:

"Starts killing in as little as 1 hour"

"Starts killing in as little as 1 hour."

11. Throughout the entire label, per the Acute Toxicity and Companion Animal Safety review, change "up to 22 lbs" to "4 to 22 lbs" to include a minimum dog weight.

12. On page 1 under the header Fleas, revise the following claims to add the underlined words, or delete struck-out words, as follows:

~~"[Controls flea reinfestation for up to 16 weeks]"~~

~~"[Research demonstrates that [brand name] kills adult fleas (starts in as little as 1 hour), flea eggs, and flea larvae and prevents pupae for up to four months.]"~~

~~"[[brand name] prevents development of all flea stages for up to four months.]"~~

"[Prevents all flea stages (adult fleas (starts killing in as little as 1 hour), flea eggs, flea pupae and flea larvae)]"

~~"[Kills flea eggs [larvae] [prevents pupae] for up to 4 months]"~~

~~"[Kills Flea Eggs & Flea Larvae [for 2 months] [up to 4 months]]"~~

"Kills all stages of the flea life cycle"

13. On pages 1 and 2 under Multiple Infestations, revise the following claims to add the underlined words, or delete struck-out words, as follows:

"[Kills fleas (starts killing in as little as 1 hour), flea eggs, ticks (starts killing in as little as 1 hour), chewing lice & mosquitoes][and prevents development of flea pupae]"

"[Kills fleas (starts killing in as little as 1 hour), ticks (starts killing in as little as 1 hour), mosquitoes, chewing lice, flea eggs, and larvae ~~and prevents pupae~~]"

"[Kills fleas (starts killing in as little as 1 hour), ticks (starts killing in as little as 1 hour), mosquitoes, flea eggs, and lice]"

"[Kills Fleas (starts killing in as little as 1 hour) and Ticks [and mosquitoes](starts killing in as little as 1 hour) for up to 4 weeks!]"

~~"[Kills Fleas (starts in as little as 1 hour), Ticks (starts in as little as 1 hour), Flea Eggs & Flea Larvae for up to 16 Weeks]"~~

"[Prevents and controls reinfestations of listed pests for up to [1 month] [4 weeks]]"

14. On page 2 under Ticks, revise the following claims to add the underlined words, or delete struck-out words, as follows:

"[Kills ticks (starts killing in as little as 1 hour)]"

"[Kills Ticks (starts killing in as little as 1 hour) for Up to [4 weeks]]!"

"[Kills [all stages of] Deer Ticks (which may vector of Lyme Disease) for up to 4 weeks]"

"[Kills Brown Dog Ticks (starts killing in as little as 1 hour)]"

15. On page 2 under All Others, revise the following claims to add the underlined words, or delete struck-out words, as follows:

~~“[Once a month treatment is recommended]”~~
~~“[[Free] Brochure and Calendar Stickers Inside]”~~
~~“[Prevents and controls reinfestations of listed pests]”~~
~~“[Free with purchase] [Free inside] Monthly Application Reminder [Magnet] {clip} [card]”~~

16. On page 3 in the Ingredients Statement, all Inert ingredients must be identified when electing to list the inert ingredients.
17. On page 3, delete the optional statement “[Ingredient Statement may be on front or back label]” because the ingredient statement must be placed on the Front Panel.
18. On page 4 under the Back Panel, revise the first sentence to read as follows:

“[brand name] contains fipronil, cyphenothrin, and the insect growth regulator (IGR) (S)-methoprene to effectively kill Fleas [(starts killing in as little as 1 hour)], Ticks [(starts killing in as little as 1 hour)], and kills mosquitoes and chewing lice.”
19. On page 6 in the How to Apply section, correct the reapplication interval from “4 weeks” to “30 days” to be consistent with the interval stated under Frequency of Application.
20. On page 6 under the Frequency of Application, add the underlined words in the following statements:

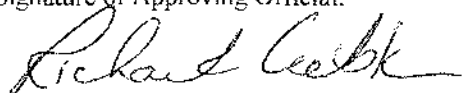
“[Studies show that] [brand name] kills fleas (starts killing in as little as 1 hour) for up to three months. If your pet is at high risk for flea reinfestation [, or in a highly infested environment], apply monthly.”

“[Brand name] kills mosquitoes within 24 hours for up to the first 7 days after treatment, then within 48 hours for up to 28 days.”
21. On page 7 under the Storage and Disposal statement, replace “Container Handling” with “Container Disposal.”
22. On page 7 in the Warranty statement, remove the brackets within the paragraph so that if used, the Warranty statement is present in its entirety.
23. On page 9 under the End-back/side Panel section, delete the “Optional Insert or Package Copy” statement because the Agency has not reviewed the optional insert as part of the labeling for approval.
24. Note that should you wish to add a reference to the company’s website on your label, then the website becomes labeling under FIFRA and is subject to review by the Agency. If the website content is false or misleading, the product would be deemed misbranded and unlawful to sell or distribute under FIFRA §12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements, or claims substantially differing from the EPA-approved registration, the website may be referred to the EPA’s Office of Enforcement and Compliance Assurance.
25. Revise the EPA Registration Number to read: “EPA Registration No. 2517-142.”

If the Agency determines that future mitigation measures are necessary for all pet spot-on products, you will be informed, and be expected to comply. If mitigation measures are necessary, the Agency may take appropriate regulatory actions. Two copies of the finished labeling must be submitted prior to releasing the product for shipment. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A copy of your label stamped "Accepted with Comments" is enclosed for your records. Please contact Rosanna Louie-Juzwiak at (703) 308-0037 with any questions.

Enclosure: Sergeant's Fipronil + Cyphenothrin + Methoprene Squeeze-on for Dogs Label, Stamped
Accepted with Comments

Signature of Approving Official:



Richard Gebken, Product Manager (10)
Registration Division, Insecticide Branch

Date:

MAR 23 2011

EPA Form 8570-6

Sergeant's® Master Label

4 March 2011

Version 10.1

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Information in [] is optional.

Page 1 of 10

FRONT PANEL

DOG SQUEEZE ON

FIPRONIL+CYPHENOTHHRIN+METHOPRENE

[Option text appears in brackets-the final product label may include some or all of the optional text on front, back or side panels. The CRP required text will not change.]

Sergeant's Fipronil + Cyphenothrin + Methoprene Squeeze-On for Dogs

[ABNs]

[(Sergeant's®) (Sentry®) FRONTIER GOLD (Spot On) for dogs]

[(Sergeant's®) (Sentry®) Ectoadvance™ (Spot On) for dogs]

[Apply to puppies over 12 weeks old]

[Apply to puppies 12 weeks or older]

ACCEPTED
with COMMENTS
In EPA Letter Dated:

MAR 23 2011

Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
2517-142

[Mosquitoes]

[•Kills mosquitoes] [within 24 hours for up to 7 days] [and within 48 hours for up to 28 days]

[•Kills mosquitoes]

[Fleas]

[•Controls flea reinfestation for up to [16 weeks]]

[•Research demonstrates that [brand name] kills adult fleas (starts in as little as 1 hour), flea eggs, and flea larvae and prevents pupae for up to four months.]

[•[brand name] prevents development of all flea stages for up to four months.]

[•Prevents all flea stages (adult fleas (starts killing in as little as 1 hour), flea eggs, flea pupae and flea larvae)]

[•If dog is a high risk for flea re-infestation a once month application may be needed]

[•Kills flea eggs [larvae] [prevents pupae] for up to 4 months]

[•With (S)-methoprene Insect Growth Regulator which Breaks the Flea Life Cycle]

[•With (S)-methoprene to Break Flea Life Cycle]

[•With Insect Growth Regulator to Break Flea Life Cycle]

[•Triple Action [!]:Fipronil and Cyphenothrin with (S)-methoprene IGR Effectively Breaks the Flea Life Cycle]

[•Triple Action [!]: Effectively Breaks the Flea Life Cycle[!]]

[•Kills Fleas (starts in as little as 1 hour) up to [4 weeks]!]

[•Kills Flea Eggs & Flea Larvae [for 2 months] [up to 4 months]!]

[•Prevents Flea Eggs From Developing Into Biting Adults]

[•Kills all stages of the flea life cycle]

[Multiple Infestations]

[•Flea & Tick Control for Dogs & Puppies 12 weeks old and older]

[•Kills fleas (starts killing in as little as 1 hour), flea eggs, ticks (starts killing in as little as 1 hour), chewing lice & mosquitoes][and prevents development of flea pupae]

[•Kills Fleas, Ticks and Mosquitoes]

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- Kills fleas (starts killing in as little as 1 hour), ticks (starts killing in as little as 1 hour), mosquitoes, chewing lice, flea eggs, and larvae and ~~prevents pupae~~
- Monthly flea, tick, mosquito, chewing lice, and flea egg protection]
- Monthly flea, tick, mosquito and chewing lice protection]
- Kills fleas (starts killing in as little as 1 hour), ticks (starts killing in as little as 1 hour), mosquitoes, flea eggs, and lice]
- [Seven] [7] Way [Action] [Effectiveness] [Control] to kill fleas, ticks, [mosquitoes,] chewing lice, flea eggs, flea larvae [&] [and] prevent the development of flea pupae]]
- [Six] [6] Way [Action] [Effectiveness] [Control] to kill fleas, ticks, [mosquitoes,] chewing lice, flea eggs [&] [and] flea larvae]
- [4 Week] [Flea and Tick & Treatment]
- [Four (4) Week] [Flea, Tick, Mosquito and Chewing Lice Control]
- When used monthly [brand name] completely breaks the flea life cycle and controls tick and chewing lice infestations.]
- 4 week Flea and Tick Treatment!]
- Once A Month Flea and Tick Treatment]
- Kills Fleas (starts killing in as little as 1 hour) and Ticks [and mosquitoes](starts killing in as little as 1 hour) for up to 4 weeks!]
- Kills Fleas (starts in as little as 1 hour), Ticks (starts in as little as 1 hour), Flea Eggs & Flea Larvae for up to 16 Weeks]
- Prevents and controls reinfestations of listed pests for up to [1 month] [4 weeks]]

[Ticks]

- Kills ticks (starts killing in as little as 1 hour)]
- Kills ticks including those that may transmit Lyme disease]
- Kills Ticks (starts killing in as little as 1 hour) for Up to [4 weeks]!]
- Kills [all stages of] Deer Ticks (which may vector of Lyme Disease) for up to 4 weeks]
- Kills Ticks (starts in as little as 1 hour)]
- Kills Ticks including Deer Ticks for up to 4 weeks]
- Kills Brown Dog Ticks (starts killing in as little as 1 hour)]
- Kills [Brown], [American,] [and Lone Star] Dog Ticks for up to 4 weeks]
- Kills *Rhipicephalus sanguineus* for up to 4 weeks]
- Kills American Dog Ticks [(*Dermacentor variabilis*)] for up to 4 weeks!]

[All Others]

- For Dogs and Puppies 12 weeks of age or older]
- For Dogs [~~up 4~~ to 22 lbs], [23-44 lbs], [45-88 lbs], [89-132 lbs]
- Fast Acting]
- Waterproof]
- Effective after bathing and exposure to water and sunlight]
- Long Lasting]
- ~~Once a month treatment is recommended]~~
- Apply monthly]
- A once monthly application is required [apply monthly to control] [for] chewing lice.]
- Rapid elimination of chewing lice infestations]
- [Controls mites that may cause sarcoptic mange]
- Three Applications] and/or [3 Month Supply] or [12 Week Supply]
- Best if used year round!]

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- [•4 Week Dose!]
- [•(ICON Showing 4 Week Protection)]
- [•1 Month Dose!]
- [•Easy to Use Application]
- [•Specially Formulated for Dogs and Puppies Over 12 Weeks]
- [•[Free] Calendar Stickers Inside!]
- [•[Free] Brochure and Calendar Stickers Inside]
- [•Apply once every [4 weeks]!]
- [•[Free with purchase] [Free inside] Monthly Application Reminder [Magnet] [clip] [card]]
- [•Effective after bathing and exposure to water and sunlight]
- [•~~Prevents and controls reinfestations of listed pests~~]
- [•~~[Free with purchase] [Free inside] Monthly Application Reminder [Magnet] [clip] [card]~~]
- [•3 applications]
- [•Fiponil (9.8%) + cyphenothrin (5.2%) + s-methoprene (8.8%)]
- [•US and Foreign patents pending]
- [•Lift [here] for more information]
- [•For year round protection, apply (brand name) monthly]

[3 Applications]

[For use ONLY on dogs]

[Up 4 to 22 lbs]

[23-44 lbs]

[45-88 lbs]

[89-132 lbs]

[over 12 weeks of age]

[For Dogs & Puppies (12 weeks or older and) up to 22 lbs.]

[For Dogs 23-44 lbs.]

[For Dogs 45-88 lbs.]

[For Dogs 89-132 lbs.]

[] - Denotes Optional Statements and/or Images that May be Used on Front, Back or Side Label Panels

~~[Ingredient Statement may be on front or back label]~~

ACTIVE INGREDIENTS:

Fipronil.....	9.8%
Cyphenothrin.....	5.2%
(S)-methoprene	8.8%
OTHER INGREDIENTS*:	<u>76.4%</u>
TOTAL:	100.0%

[*diethylene glycol monoethyl ether]

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KEEP OUT OF REACH OF CHILDREN

WARNING

See [Back][or][Side] [Label Panel[s] for Additional Precautionary Statements

NET CONTENTS:

Contains (3) [0.023 fl oz] [0.67 ml] applicators

Contains (3) [0.045 fl oz] [1.34 ml] applicators

Contains (3) [0.091 fl oz] [2.68 ml] applicators

Contains (3) [0.136 fl oz] [4.02 ml] applicators

BACK PANEL

DOG SQUEEZE ON

FIPRONIL+CYPHENOTHHRIN+METHOPRENE

[BACK/SIDE CARTON LABEL - MASTER LABEL]

[brand name] contains fipronil, cyphenothrin, and the insect growth regulator (IGR) (S)-methoprene to effectively kill Fleas [(starts killing in as little as 1 hour)], Ticks [(starts killing in as little as 1 hour)], and kills mosquitoes and chewing lice. The active ingredients in [brand name] feature a sustained release formula developed for fast acting [and long lasting] control of fleas, ticks, [mosquitoes] and chewing lice for up to [1 month] [[4] [four] weeks] on dogs.

READ ENTIRE LABEL BEFORE EACH USE.

USE ONLY ON DOGS AND PUPPIES OVER 12 WEEKS OF AGE.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. WARNING. Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Harmful if swallowed. Harmful if absorbed through skin. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

HAZARDS TO DOMESTIC ANIMALS. For external use only. Do not use on puppies under 12 weeks of age. Individual sensitivities, while rare, may occur after using any pesticide product. [Some dogs may experience temporary startle effects when any product is applied.] Dogs may experience some temporary irritation at the site of product application. If signs persist, or become more severe within a few days of application, consult a veterinarian immediately. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating treatment. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, pregnant, nursing, debilitated or aged dogs. Call 1-800-781-4738 for 24-hour assistance.

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FIRST AID	
If In Eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for further treatment advice.
If On Skin Or Clothing	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
If Swallowed	<ul style="list-style-type: none">• Immediately call a poison control center or doctor.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Have person sip a glass of water if able to do so.• Do not give anything by mouth to an unconscious person.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For more information on this pesticide product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-781-4738.	
NOTE TO PHYSICIAN OR VETERINARIAN	
Treat patient symptomatically	

BACK PANEL

DOG SQUEEZE ON FIPRONIL+CYPHENOTHHRIN+METHOPRENE

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

DO NOT ALLOW CHILDREN TO APPLY PRODUCT. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON DOGS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS.

DO NOT USE ON CATS. May be toxic and potentially fatal if applied to or ingested by cats. **FOR EXTERNAL USE ON DOGS ONLY.** Do not use on puppies under 12 weeks of age. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Do not treat your dog with more than one pesticide product at a time. Over dosing your dog can result in serious illness and even death. **Best if used year round.** Certain medications can interact with pesticides. Consult a veterinarian before using this product on debilitated, aged, medicated, pregnant, or nursing dogs. Consult a veterinarian before using on dogs with known organ dysfunction. **DO NOT USE ON CATS** or animals other than dogs. Separate the treated dog from all other dogs and cats for 24 hours after treatment has been applied. Cats and dogs that actively groom or engage in close physical contact with treated dog may be at risk of serious harmful effects. The most common signs of ingestion are excessive salivation and foaming at the mouth. If these symptoms occur immediately feed your dog and continue to monitor your pet for the next 24 hours. If symptoms persist call 1-800-781-4738 to talk to a veterinarian. Cats exhibiting these same symptoms from ingestion should be taken to the veterinarian immediately.

Sergeant's[®] Master Label

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Information in [] is optional.

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If your dog is exhibiting signs of and/or are being treated for skin dermatitis, talk to your vet before applying any topical flea and tick control product.

Sensitivities may occur after using ANY pesticide product on dogs. Dogs may experience some temporary irritation at the site of product application. If signs of sensitivity occur bathe your dog with a mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately by calling 1-800-781-4738.

[{Outer Packaging}]

How to open: Remove product tubes [vial] from the package. Separate one tube from the others. Holding the tube [vial] with notched end pointing up and away from the face and body, cut off the narrow end at the notches with scissors.

How to apply: Invert tube over dog and use open end to part dog's hair. Squeeze tube firmly to apply all of the solution to the dog's skin, as directed below. Repeat application may be made if necessary, but do not apply more often than once every 30 days 4-weeks.



[Optional drawings that may or may not appear on finished label]

FREQUENCY OF APPLICATION

Use [brand name] monthly for complete control of flea, tick [and] chewing lice [and to kill mosquitoes] [infestations]. [Studies show that] [brand name] kills fleas (starts killing in as little as 1 hour) for up to three months. If your pet is at high risk for flea reinfestation [, or in a highly infested environment], apply monthly. Apply monthly to control ticks, mosquitoes and chewing lice. [Brand name] kills mosquitoes within 24 hours for up to the first 7 days after treatment, then within 48 hours for up to 28 days. [Brand name] remains effective, even after bathing, water immersion, or exposure to sunlight. Allow treated area to dry thoroughly. Do not reapply for 30 days.

Sergeant's® Master Label

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Information in [] is optional.

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BACK PANEL

DOG SQUEEZE ON

FIPRONIL+CYPHENOTHHRIN+METHOPRENE

For Dogs Weighing up 4 to 22 lbs. [including small dogs and puppies, 12 weeks or older]

{For cartons containing .67 ml (0.023 fl. oz.) applicator tubes}

Apply one tube (.67 ml)(0.023 fl. oz.) [as a spot to the dog's back between the shoulder blades]
[from the back of the neck to a point midway between the neck and tail].

For Dogs Weighing Between 23 - 44 lbs.

{For cartons containing 1.34 ml (0.045 fl. oz.) applicator tube}

[Apply one tube (1.34 ml) (0.045 fl. oz.) as a spot to the dog's back between the shoulder
blades.] [from the back of the neck to a point midway between the neck and tail].

For Dogs Weighing Between 45 - 88 lbs.

{For cartons containing 2.68 ml (0.091 fl. oz.) applicator tube}

Apply one tube (2.68 ml)(0.091 fl. oz.) [as a spot on the dog's back between the shoulder blades]
[from the back of the neck to a point midway between the neck and tail].

For Dogs Weighing 89 - 132 lbs.

{For cartons containing 4.02 ml (0.136 fl. oz.) applicator tube}

Apply one tube (4.02 ml)(0.136 fl. oz.) [as a spot on the dog's back between the shoulder blades]
[from the back of the neck to a point midway between the neck and tail].

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Do not remove tube from the pack until ready to use. Store in a cool
[below 77°F (25°C)] dry place inaccessible to children and pets. Do not refrigerate. Protect
from direct sunlight.

CONTAINER DISPOSAL HANDLING: **If empty:** Non-refillable container. Do not reuse or
refill this container. Offer for recycling if available. **If partly filled:** Call your local solid waste
agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

[WARRANTY

Read the entire Directions for Use and Warranty before using this Product. By using this
product, user or buyer accepts the following warranty. {{The directions for use of this product
are believed to adequate and must be followed carefully. It is impossible to eliminate all risks
associated with the use of this product. Unintended consequences may result because of
unknown factors. All such risks shall be assumed by the user or buyer.}} Sergeant's is
committed to providing high quality products. To the extent consistent with applicable law,
Sergeant's makes no warranties, express or implied, of merchantability or of fitness for a
particular purpose or otherwise, that extend beyond statements on this label. To the extent
consistent with applicable law, Sergeant's, the manufacturer, or the Seller shall not be liable for
indirect, special, incidental or consequential damages. To the extent consistent with applicable
law, the exclusive remedy of the user or buyer shall not exceed the purchase price paid.]

[If you have questions or comments about this product, please write: Sergeant's Consumer
Response, P.O. Box 540399, Omaha, NE 68154-0399.]

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Information in [] is optional.

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In Case of Emergency, call: 1-800-781-4738 [For more information] [Visit us at:]

[www.sergeants.com]

Non-Emergency call 1-800-224-PETS (7387) [Made in USA]

Distributed by:

Sergeant's Pet Care Products, Inc.

P.O. Box 540399

Omaha, NE 68154-0399

EPA Reg. No. 2517-RUE

EPA Est. No. XXXXX-XX-XXX

[BAR CODE AREA]

[How to Apply - May contain graphics illustrating product use, e.g., dog with a drop falling onto its neck from a vial on front, side, or back carton label and/or applicator labeling.]

[{Outer Packaging}]

[Application Instructions] [Directions for Use]

How to open

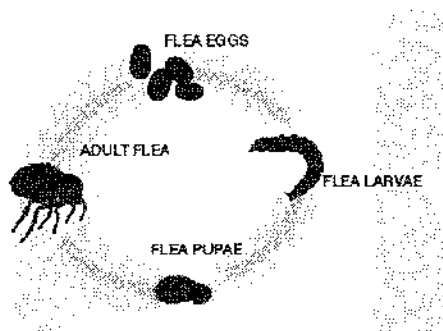
1. Remove product tubes [vial] from the package.
2. Separate one tube from the others. Holding the tube [vial] with notched end pointing up and away from the face and body, cut off the narrow end at the notches with scissors.

How to apply:

1. Invert tube over dog and use open end to part dog's hair.
2. Squeeze tube firmly to apply all of the solution to the dog's skin [as a spot to the dog's back between the shoulder blades.] [or] [from the back of the neck to a point midway between the neck and tail.]



[Flea life cycle diagram] [Flea Life Cycle][Sample coloring and layout may be different on final label]



[Look at the Label (Look at the Label icon) [Easy] 6 Step [Spot On] [Squeeze-On] [Topical] Checklist

- Read the label completely and follow directions

Sergeant's® Master Label

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Information in [] is optional.

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- Weigh your pet
- Do NOT use Dog products on Cats
- Do NOT treat with more than one pesticide product at a time
- Separate animals after treatment to avoid chance of ingestion
- Do NOT split tubes between pets]

[Brand Name]

[3] [Month] [Treatment] [Application] Tracker]

[For year-round protection, apply [Brand name] monthly.]

[Pet's Name (Empty blank for owner to fill in name)]

[First] [1st] [Second] [2nd] [Third] [3rd]

[Dose] [Treatment] [Application] (Empty blank for owner to fill in date) (Date: MM/DD/YY)]

[calendar stickers with **brand name**]

[Place stickers on your calendar as a reminder to reapply [brand name] [in 30 days.]

[Monthly Application Reminder Magnet (image of reminder magnet)]

[Enclosed for your convenience is an application reminder magnet. Push the (reset) button, and the reminder light will blink twice. The reminder tag is now set for 30 days. At the end of 30 days the reminder light will blink, reminding you to reapply [Brand name]. Press the button once and the blinking light will stop. Press the button again and this will reset the timer for another 30 days.]



Adult Flea



Adult Flea



flea eggs



flea eggs



flea larvae



flea larvae



flea pupae



flea pupae



ticks



ticks



Brown Dog Tick



Brown Dog Tick



Deer Tick



Deer Tick



American Dog Tick



American Dog Tick



chewing lice



chewing lice



Lone Star Tick



Lone Star Tick



mosquitoes



mosquitoes

[Optional graphics above may or may not appear on finished label]

~~{END - OPTIONAL INSERT OR PACKAGE COPY}~~

Sergeant's[®] Master Label

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Information in [] is optional.

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TUBE / VIAL LABEL

Front Label

{Brand Name}		DO NOT USE ON CPTS
Fipronil 9.8% w/w, Cyphenothrin 5.2% w/w, (S)-methoprene 8.8% w/w 0.023 fl oz (or) 0.045 fl oz (or) 0.091 fl oz (or) 0.136 fl oz {label code}		

Back Label

KEEP OUT OF REACH OF CHILDREN
WARNING: Read directions and precautions
before using. Use scissors to open.
EPA REG. No. 2517-RUE {label code}

Brand Y[™] for dogs

READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS AND PUPPIES OVER 12 WEEKS OF AGE.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. WARNING. Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Harmful if swallowed. Harmful if absorbed through skin. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

HAZARDS TO DOMESTIC ANIMALS. For external use only. Do not use on puppies under 12 weeks of age. Individual sensitivities, while rare, may occur after using any pesticide product. Some dogs may experience temporary stinging effects when any product is applied. Dogs may experience some temporary irritation at the site of product application. If a dog persists, or becomes more severe within a few days of application, consult a veterinarian immediately. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating treatment. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, pregnant, nursing, debilitated or aged dogs. Call 1-800-781-4738 for 24-hour assistance.

FIRST AID

If In Eyes	<ul style="list-style-type: none"> Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present. After the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for further treatment advice.
If On Skin Or Clothing	<ul style="list-style-type: none"> Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
If Swallowed	<ul style="list-style-type: none"> Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

HOTLINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For more information on this pesticide product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-781-4738.

NOTE TO PHYSICIAN OR VETERINARIAN

Treat patient symptomatically.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. **DO NOT ALLOW CHILDREN TO APPLY PRODUCT. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON DOGS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS.**

DO NOT USE ON CATS. May be toxic and potentially fatal if applied to or ingested by cats. **FOR EXTERNAL USE ON DOGS ONLY.** Do not use on puppies under 12 weeks of age. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Do not treat your dog with more than one pesticide product at a time. Over dosing your dog can result in serious illness and even death. Best if used year round. Certain medications can interact with pesticides. Consult a veterinarian before using this product on debilitated, aged, malnourished, pregnant, or nursing dogs. Consult a veterinarian before using on dogs with known organ dysfunction. **DO NOT USE ON CATS** or animals other than dogs. Separate the treated dog from all other dogs and cats for 24 hours after treatment has been applied. Cats and dogs that actively groom or engage in close physical contact with treated dog may be at risk of serious harmful effects. The most common signs of ingestion are excessive salivation and foaming at the mouth. If these symptoms occur immediately feed your dog and continue to monitor your dog for the next 24 hours. If symptoms persist call 1-800-781-4738 to talk to a veterinarian. Cats exhibiting these same symptoms from ingestion should be taken to the veterinarian immediately. If your dog is exhibiting signs of an injury being treated for skin dermatitis, talk to your vet before applying any topical flea and tick control product.

Sensitivities may occur after using ANY pesticide product on dogs. Dogs may experience some temporary irritation at the site of product application. If signs of sensitivity occur bathe your dog with a mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately by calling 1-800-781-4738.

How to open: Remove product tubes from the package. Separate one tube from the others. Holding the tube with notched end pointing up and away from the face and body, cut off the narrow end at the notches with scissors.

How to apply: Insert tube over dog and use open end to pad dog's hair. Squeeze tube firmly to apply all of the solution to the dog's skin, as directed below. Repeat application may be made if necessary, but do not apply more often than once every 4 weeks.

FREQUENCY OF APPLICATION

Use Brand Y[™] monthly for complete control of flea, tick and chewing lice infestations. Studies show that Brand Y[™] kills adult fleas for up to three months. If your pet is at high risk for flea reinfestation, apply monthly. Apply monthly to control ticks, mosquitoes, and chewing lice. Brand Y[™] kills mosquitoes within 24 hours for the first 7 days after treatment, then within 48 hours for up to 28 days. Brand Y[™] remains effective even after bathing, water immersion, or exposure to sunlight. Allow treated area to dry thoroughly. Do not reapply for 30 days.

For Dogs Weighing Up to 22 lbs: Apply one tube (0.67 mL) (0.023 fl oz) as a spot to the dog's back between the shoulder blades.

If you have questions or comments about this product, please write: SENTRY Consumer Response, P.O. Box 540399, Omaha, NE 68154-0399.

Distributed by: Sergeant's Pet Care Products, Inc., P.O. Box 540399, Omaha, NE 68154-0399, EPA Reg. No. 2517-RUE, EPA Est. No. 2517-TM-1

U.S. and Foreign Patents Pending

Made in USA

In Case of Emergency, call: 1-800-781-4738

Non-Emergency call 1-800-224-PETS (7367)

309000X 4218

for dogs
Brand Y[™]

Up to 22 lbs
over 12 weeks of age

For use ONLY on dogs

3 Applications

SENTRY

Brand Y[™] for dogs



Brand Y[™]
for dogs
For use ONLY on dogs
Up to 22 lbs
over 12 weeks of age

KILLS
fleas
flea eggs
ticks
chewing lice
mosquitoes

Controls mites that may cause sarcoptic mange
Waterproof

ACTIVE INGREDIENTS:

Fipronil	9.80%
Cyphenothrin	5.20%
(S)-methoprene	8.80%
OTHER INGREDIENTS*	76.40%
TOTAL:	100.00%
*Diethylene Glycol Monoethyl Ether, Vitamin E Nicotinate	

KEEP OUT OF REACH OF CHILDREN
WARNING

See Back Label Panel for Additional Precautionary Statements

Net Contents: Three 0.023 fl oz (0.67 mL) applicators



STORAGE AND DISPOSAL

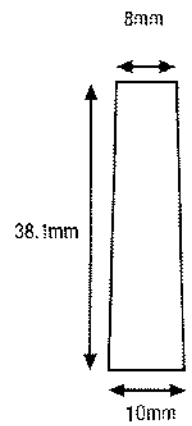
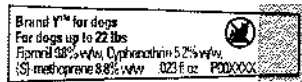
PESTICIDE STORAGE: Do not remove tube from the pack until ready to use. Store in a cool (below 77°F/25°C), dry place inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.
CONTAINER DISPOSAL: If empty: Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.




EPA Reg # 2517-RUE



Front

White tube / Black text on a white label / Colored Strip



PROJECT NAME & PROJECT NUMBER	DATE	DRAFT#	DIMENSIONS	UPC CODE	PART#
Brand Y for Dogs up to 22lbs T-Label	14MAR11	2		UPC 0 73091 XXXXX X	P00XXXX
<p>ART INSTRUCTION FOR THE PRINTER</p> <div style="display: flex; justify-content: space-around; align-items: flex-start;"> <div style="text-align: center;">  BLACK </div> <div style="text-align: center;">  PMS 165 </div> <div style="text-align: right;"> <p>Printer/Vendor: _____ Date sent: _____</p> <p>Additional Notes: _____</p> </div> </div> <p style="text-align: center; margin-top: 20px;">Labels adhere to White Tubes</p> <div style="text-align: right; margin-top: 10px;">  </div>					

2517-142 MAR 29 2011

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MAR 99

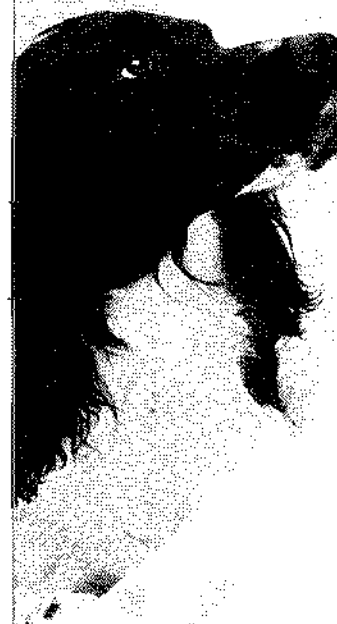
3 Applications

SENTRY

For use ONLY on dogs

23-44 lbs
over 12 weeks of age

Brand YTM for dogs



KILLS

- fleas
- flea eggs
- ticks
- chewing lice
- mosquitoes

- Controls mites that may cause sarcoptic mange
- Waterproof

ACTIVE INGREDIENTS:

Isipronil 9.80%
Cyphenothrin 5.20%
(S)-methoprene 8.80%

OTHER INGREDIENTS*: 76.40%

TOTAL: 100.00%

*Diethylene Glycol Monoethyl Ether,
Vitamin E Nicotinate

KEEP OUT OF REACH OF CHILDREN
WARNING

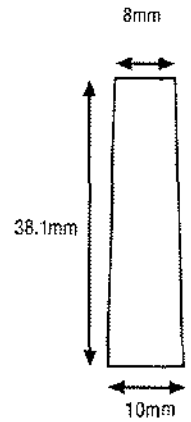
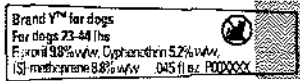
See Back Label Panel for Additional Precautionary Statements




Net Contents: Three 0.045 fl oz
(1.34 mL) applicators



Front

White tube / Black text on a white label / Colored Strip



PROJECT NAME & PROJECT NUMBER	DATE	DRAFT#	DIMENSIONS	UPC CODE	PART#
Brand Y Dogs 23-44 LBs T-Label	15MAR11	1		UPC 0 73091 XXXXX X	P00XXXX
<p>ART INSTRUCTION FOR THE PRINTER</p> <div style="display: flex; justify-content: space-around;"> <div style="text-align: center;">  BLACK </div> <div style="text-align: center;">  FMS 363 </div> </div> <p>Printer/Vendor: _____ Date sent: _____</p> <p>Additional Notes: _____</p> <p style="text-align: center;">Labels adhere to White Tubes</p> <div style="text-align: right;">  </div>					

2517-142

MAR 23 2011

2517-142

MAR 93

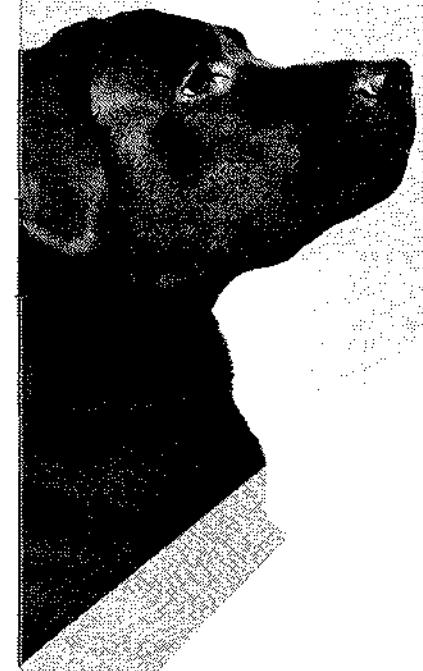
3 Applications

SENTRY.

For use ONLY on dogs

45-88 lbs
over 12 weeks of age

Brand YTM for dogs



KILLS

- fleas
- flea eggs
- ticks
- chewing lice
- mosquitoes

- Controls mites that may cause sarcoptic mange
- Waterproof

ACTIVE INGREDIENTS:

Fipronil.....9.80%
Cyphenothrin.....5.20%
(S)-methoprene.....8.80%

OTHER INGREDIENTS*:.....76.40%

TOTAL:.....100.00%

*Diethylene Glycol Monoethyl Ether,
Vitamin E Nicotinate

KEEP OUT OF REACH OF CHILDREN
WARNING

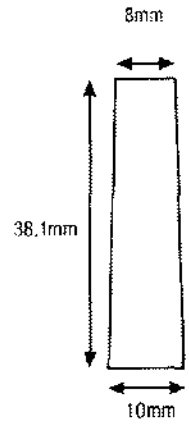
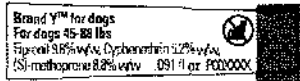
See Back Label Panel for Additional Precautionary Statements




Net Contents: Three 0.091 fl oz
(2.68 mL) applicators



Front

White tube / Black text on a white label / Colored Strip



PROJECT NAME & PROJECT NUMBER	DATE	DRAFT#	DIMENSIONS	UPC CODE	PART#
BRAND Y for Dogs 45-88lbs T-label	15MAR11	1		UPC 0 73091 XXXXX X	P00XXXX
<p>ART INSTRUCTION FOR THE PRINTER</p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  BLACK </div> <div style="text-align: center;">  PMS 200 </div> </div> <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <p>Printer/Vendor:</p> <p>Date sent:</p> </div> <p>Additional Notes:</p> <p style="text-align: center; margin-top: 20px;">Labels adhere to White Tubes</p> <div style="text-align: right; margin-top: 10px;">  </div>					

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MAR 23 2011

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MR 03 00

3 Applications

SENTRY

For use ONLY on dogs

89-132 lbs
over 12 weeks of age

Brand YTM for dogs



KILLS

- fleas
- flea eggs
- ticks
- chewing lice
- mosquitoes

- Controls mites that may cause sarcoptic mange
- Waterproof

ACTIVE INGREDIENTS:

Fipronil	9.80%
Cyphenothrin	5.20%
(S)-methoprene	8.80%
OTHER INGREDIENTS*	76.40%
TOTAL:	100.00%
*Diethylene Glycol Monoethyl Ether, Vitamin E Nicotinate	

KEEP OUT OF REACH OF CHILDREN

WARNING

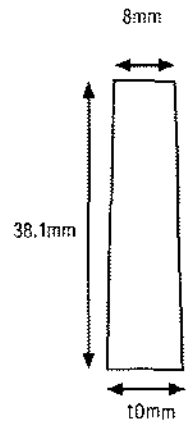
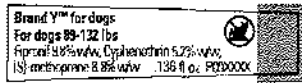
See Back Label Panel for Additional Precautionary Statements




Net Contents: Three 0.136 fl oz
(4.02 mL) applicators



Front

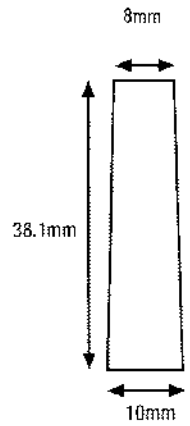
White tube / Black text on a white label / Colored Strip





PROJECT NAME & PROJECT NUMBER	DATE	DRAFT#	DIMENSIONS	UPC CODE	PART#
BRAND Y for Dogs 89-132Lbs T-Label	15MAR11	1		UPC 0 73091 XXXXX X	PO0XXXX
<p>ART INSTRUCTION FOR THE PRINTER</p> <div style="display: flex; justify-content: space-around;"> <div style="text-align: center;">  BLACK </div> <div style="text-align: center;">  PMS 2945 </div> </div> <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <p>Printer/Vendor:</p> <p>Date sent:</p> </div> <p>Additional Notes:</p> <p style="text-align: center; margin-top: 20px;">Labels adhere to White Tubes</p> <div style="text-align: right; margin-top: 10px;">  </div>					

2517-142 MAR 23 11

Back Tube Label



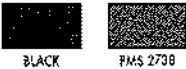

KEEP OUT OF REACH OF CHILDREN
 WARNING: Read directions and precautions
 before using. Use scissors to open.
 EPA REG. No. 2517-RUE P00XXXX

PROJECT NAME & PROJECT NUMBER	DATE	DRAFT#	DIMENSIONS	UPC CODE	PART#
Brand Y Back Tube Label	15MAR11	1			P00XXXX
<p>ART INSTRUCTION FOR THE PRINTER</p> <div style="display: flex; justify-content: space-between;"> <div>  BLACK </div> <div> Printer/Vendor: _____ Date sent: _____ Additional Notes: _____ </div> </div> <p style="text-align: center;">Labels adhere to White Tubes</p> <div style="text-align: right;">  </div>					

2517-142 MAR 23 2011





PROJECT NAME & PROJECT NUMBER	DATE	DRAFT#	DIMENSIONS	UPC CODE	PART#
Pawprint Sticker	02NOV10	1		UPC 0 73091 XXXXX X	P00XXX
ART INSTRUCTION FOR THE PRINTER					
 BLACK FMS 2738		Printer/Vendor:		Date sent:	
		Additional Notes:			
					

2517-142

MAR 23 10

Decision Information for 2517 RUE

Decision Seq: 438361	Action Code: R310, NEW PRODUCT, NON-FAST TRACK (INCLUDES REVIEWS)		Decision Status
Tentative Start Date: 01-Sep-2010	Tentative Ind: Yes	FFS Original Decision: ...	Tracking
Tentative Due Date: 01-Mar-2011	75-Day Due Date: ...	FFS EUP Decision: ...	Create Resubmission
OPP Target Due Dt: ...	21-Day Screen Dt: 01-Sep-2010	FFS Primary Decision: ...	FFS Letters
Negotiated Due Dt: ...	Start/Stop Clock: ...	FQPA Clock: ...	
Registrant: ...	Days Elapsed: ...		Action Code History
Response Due Date: ...			Secondary Decision
Current Status: PENDING (12-Aug-2010)			

<input type="checkbox"/> Decision Comments	<input type="checkbox"/> Payment	<input type="checkbox"/> Unmatched Payments	<input type="checkbox"/> 75 Day Letters
<input type="checkbox"/> Meetings & Milestones	<input type="checkbox"/> FFS Information	<input type="checkbox"/> FFS Negotiated Due Dates	<input type="checkbox"/> OPP Target Due Date
<input type="checkbox"/> Decision Ownership	<input type="checkbox"/> Receipts	<input type="checkbox"/> Data Package	<input type="checkbox"/> Reduced Risk

Receipts	Staff Member	Reg/DCI Number	Submission Due Dt	Response
S:880182	Louie, Rosanna	2517-RUE	01-Mar-2011	PENDING

NEW END-USE PRODUCT REGISTRATION APPLICATION

COMPLETED

30 Aug: Received: awaiting payment and new PRIA date

4 Oct. (next to R310)

5 Oct: CEN: 332785 ✓ EX: 332789 ✓ (COMPAN): 332790 ✓ ERP: 332791 ✓ E: 332792

↳ do DRAFT Label Review, get clean from Marissa.

2 more drafts to go

DATA PACKAGE BEAN SHEET

Date: 05-Oct-2010

Page 1 of 3

Decision #: 438361

DP #: (382788)

PRIA

Parent DP #:

Submission #: 880182

*** Registration Information ***

Registration: 2517-RUE - SERGEANT'S FIPRONIL + CYPHENOTHHRIN + METHOPREN

Company: 2517 - SERGEANT'S PET CARE PRODUCTS, INC.

Risk Manager: RM 10 - Richard Gebken - (703) 305-6701 Room# PY1 S-7237

Risk Manager Reviewer: Rosanna Louie RLOUIE

Sent Date: _____

Calculated Due Date: 23-Mar-2011

Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (R310) NEW PRODUCT;NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT CHEMIST

Ingredients: See page 3

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 05-Oct-2010

Due Back: _____

DP Ingredient: See page 3

DP Title: #2517-RUE: Product Chemistry Review

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #: _____

Assigned To

Date In

Date Out

Organization: RD / TRB

Last Possible Science Due Date: 21-Feb-2011

Team Name: CHEM

Science Due Date: _____

Reviewer Name: Shyam Markey

2/18/11

3/1/11

Sub Data Package Due Date: _____

Contractor Name: _____

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

No Additional Data Packages

*** Data Package Instructions ***

Attn TRB/CHEM: Please conduct a product chemistry review of the attached package in support of the proposed product. Contact Rosanna Louie-Juzwiak at 308.0037 with any questions.

Attachments:

- cover letter
- basic CSF
- draft label
- MRIDs 48189201, -02

DATA EVALUATION RECORD

FIPRONIL
CYPHENOTHHRIN
S-METHOPRENE

(Sergeant's Fipronil + Methoprene Squeeze-On for Dogs)

STUDY TYPES: Product Identity and Composition (OPPTS 830.1550)
Description of Materials Used to Produce the Product (OPPTS 830.1600)
Description of Production Process (830.1620)
Discussion of Formation of Impurities (OPPTS 830.1670)
Preliminary Analysis (OPPTS 830.1700)
Certified Limits (OPPTS 830.1750)
Enforcement Analytical Method (OPPTS 830.1800)
Physical and Chemical Characteristics (OPPTS 830.6302-830.7950)

MRIDs 481892-01 and 481892-02

Prepared for
Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Environmental Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Task Order No. 1-43

Primary Reviewer:
Eric B. Lewis, M.S.

Signature: Eric B. Lewis
Date: JAN 11 2011

Secondary Reviewers:
Sylvia Milanez, Ph.D., D.A.B.T.

Signature: Sylvia Milanez
Date: JAN 11 2011

Robert H. Ross, M.S., Group Leader

Signature: Robert H. Ross
Date: JAN 11 2011

Quality Assurance:
Kimberly G. Slusher, M.S.

Signature: Kimberly G. Slusher
Date: JAN 11 2011

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory managed and operated by UT-Battelle, LLC., for the U.S. Department of Energy under Contract No. DE-AC05-00OR22725.

DP BARCODE No.: D382788; FILE SYMBOL No.: 2517-RUE; DECISION No.: 438361;
PC Code(s): 129013, 129121, 105402; Action Code: R 310; FOOD Use: No

DATE OUT: March 1, 2011

SUBJECT: End Use Product Chemistry Review
Product Name: Sergeant's Fipronil + Cyphenothrin + Methoprene Squeeze-On for Dogs

FROM: Shyam Mathur
Product Chemistry Team
Technical Review Branch / Registration Division (7505P)

TO: Rosanna Louie / Richard Gebken, PM 10
Insecticide Branch / Registration Division (7505P)

Company Name: Sergeant's Pet Care Products, Inc.
Formulation Type: Insecticide

A. INTRODUCTION:

The applicant submitted an application for registration of a new non-food use end use product. In support of the application, the applicant submitted product chemistry data corresponding to guideline 830 series, group A & group B (MRIDs 481892-01 and 481892-02). A CSF for a basic formulation (dated 8/11/2010) was submitted along with the product label. On the advice of the Agency, the registrant submitted a revised basic CSF and an alternate CSF #1 (both dated 02-28-11) by e-mail on February 28, 2011. The primary review of the product chemistry data was performed by Oak Ridge National Laboratory, Oak Ridge, TN, USA. TRB has been asked to determine the acceptability of the product chemistry data and the proposed CSF's.

B. SUMMARY OF FINDINGS:

1. Name of Active Ingredient(s): Fipronil (9.8%), S-Methoprene (8.8%), Cyphenothrin (5.2%)
2. All the source materials for the active ingredients are derived from registered sources:
☒ Yes; ☐ No
3. All inert ingredients have been screened by IIAB and found to be approved for the proposed labeled uses
☒ Yes; ☐ No.
4. Confidential Statement of Formula(s):

☒ Basic - Dated: August 11, 2010; Re-submitted (email 02-28-11) – Dated: 28 February, 2011

☒ Alternate # 1 - Dated: 02-28-11

Is the alternate CSF in compliance with 40CFR§152.43?

☒ Yes; ☐ No; ☐ NA

DP BARCODE No.: D382788; FILE SYMBOL No.: 2517-RUE; DECISION No.: 438361;
PC Code(s): 129013, 129121, 105402; Action Code: R 310; FOOD Use: No

5. Product label

- a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concurs with product label (PR Notice 91-2)

☒ Yes, if not, explain below:

Metallic equivalent: ☐ Yes ☒ NA;

Soluble arsenic: ☐ Yes ☒ NA

Isomeric ratios: ☐ Yes ☒ NA

Acid equivalent: ☐ Yes ☒ NA; {name} acid equivalent = xx %

- b. Health related sub statements: Product contains?

Petroleum distillate at > 10%: ☐ Yes ☒ No ☐ NA

Methanol at > 4%: ☐ Yes ☒ No ☐ NA

- c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown?

☐ Yes ☒ No

Is the sub statement in compliance with PR Notice 97-6? ☐ Yes, ☒ NA; ☐ No; if not, explain below:

- d. Label requires an additional Storage and Disposal statement: ☐ Yes ☒ No; if yes explain below:

DP BARCODE No.: D382788; FILE SYMBOL No.: 2517-RUE; DECISION No.: 438361;
PC Code(s): 129013, 129121, 105402; Action Code: R 310; FOOD Use: No

6. Group A: Product Chemistry Data

TRB's determination of the acceptability of the data for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		TRB's Assessment of Data	MRID Nos.
			Yes	No		
830.1550	Product Identity & Composition		X		A	481892-01
830.1600	Description of materials used to produce the product		X		A	481892-01
830.1650	Description of formulation process		X		A	481892-01
830.1670	Discussion on the formation of impurities		X		A	481892-01
830.1700	Preliminary analysis			X	NA	
830.1750	Certified limits (158.350)	Standard certified limits	X		A	481892-01
		Proposed Limits				
		Justification for wider limits				
830.1800	Enforcement analytical method			X	G	

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver Request, I = In Progress,
NA = Not Applicable

DP BARCODE No.: D382788; FILE SYMBOL No.: 2517-RUE; DECISION No.: 438361;
 PC Code(s): 129013, 129121, 105402; Action Code: R 310; FOOD Use: No

7. Group B:

Guideline No.	Study Title	Value or Qualitative Description	TRB's Assessment of Data	MRID Nos.
830.6303	Physical State	Liquid	A	481892-02
830.6315	Flammability	Flashpoint >90°C	A	481892-02
830.6316	Explosibility	Does not contain explosive ingredients	NA	481892-02
830.7000	pH	Not soluble/dispersible in water	NA	481892-02
830.7300	Density (units)	1.00 – 1.05 g/cc	A	481892-02

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver request, NA = Not applicable,
 I = In progress

DP BARCODE No.: D382788; **FILE SYMBOL No.:** 2517-RUE; **DECISION No.:** 438361;
PC Code(s): 129013, 129121, 105402; **Action Code:** R 310; **FOOD Use:** No

C. CONCLUSIONS:

The TRB has reviewed the CSF(s) and product chemistry data for the proposed end use product and has concluded:

1. The proposed revised CSF for basic formulation (dated 02-28-11) and the new CSF for alternate formulation #1 (dated 02-28-11) are acceptable.
2. The data submitted corresponding to guidelines 830.1600 (description of materials used to produce the product), 830.1650 (description of the formulation process), 830.1670 (discussion of the formation of impurities), and 830.1750 (certified limits) are acceptable.
3. No data was submitted for the guideline 830.1800 (enforcement analytical method), this was considered as a data gap. The registrant is advised to provide a validated enforcement analytical method for the determination of the three active ingredients in the proposed product. This is a product specific data and is required to satisfy the product chemistry data requirements.
4. The product chemistry data submitted corresponding to guidelines 830.6302 (color), 830.6303 (physical state), 830.6304 (odor), 830.6315 (flammability), 830.7100 (viscosity), and 830.7300 (density) are acceptable.
5. No data were submitted for guidelines 830.6317 (storage stability) and 830.6320 (corrosion characteristics). The registrant states that these data will be submitted when the studies are completed. It is recommended that the observations should be made at 0, 3, 6, 9, and 12 month intervals.
6. The proposed label was screened as it pertains to the product chemistry requirements. The final review of the proposed label and uses are the purview of the RM team.
7. The registrant is advised to revise the Ingredient statement on the product label to correct the product label claim for the active ingredient cyphenothrin from 5.0% to 5.2%, so that it concurs with nominal concentration in the revised basic CSF (dated 02-28-11).



RE: 2517-RUE

James Messina to: Shyam Mathur

02/28/2011 04:49 PM

Shyam,

Good point. We have spoken with the PM and are planning to send updated labels to them this week.

Regards,
Jim

-----Original Message-----

From: Mathur.Shyam@epamail.epa.gov [mailto:Mathur.Shyam@epamail.epa.gov]
Sent: Monday, February 28, 2011 3:50 PM
To: James Messina
Subject: Re: 2517-RUE

Thanks James. You may have to revise the product label also for cyphenothrin to 5.2% and adjust the amounts of Other ingredients.

shyam
Shyam Mathur, Ph.D
Product Chemistry Team Leader
Technical Review Branch/Registration Division
OPP / USEPA
703-308-9374

From: "James Messina" <jmessina@exponent.com>
To: Shyam Mathur/DC/USEPA/US@EPA
Cc: "Kelly Hoskins" <KHoskins@SERGEANTS.com>, "Matthew Feinberg" <mfeinberg@exponent.com>, "Paulina Do" <pdo@exponent.com>, "Ryan Weidling" <rweidling@exponent.com>
Date: 02/28/2011 03:36 PM
Subject: 2517-RUE

Shyam,

As requested today, please find attached updated CSF's (Basic and Alternate #1) for 2517-RUE (Sergeant's Fipronil + Cyphenothrin + Methoprene Squeeze-On for Dogs. We have separated the CSF into a Basic and Alternate #1 as per EPA policy. Additionally, we have updated the percentage of cyphenothrin from 5.0% to 5.2%. This change was already approved by EPA for 2517-140 and should also be acceptable for 2517-RUG.

If you have any questions, please contact me.

Best Regards,

James Messina
Senior Managing Regulatory Consultant
Exponent
Center for Chemical Regulation and Food Safety
1150 Connecticut Avenue, N.W.
Suite 1100

DATA PACKAGE BEAN SHEET

Date: 05-Oct-2010

Page 1 of 3

Decision #: 438361

DP #: (382790)

PRIA

Parent DP #:

Submission #: 880182

*** Registration Information ***

Registration: 2517-RUE - SERGEANT'S FIPRONIL + CYPHENOTHRIIN + METHOPRENI

Company: 2517 - SERGEANT'S PET CARE PRODUCTS, INC.

Risk Manager: RM 10 - Richard Gebken - (703) 305-6701 Room# PY1 S-7237

Risk Manager Reviewer: Rosanna Louie RLOUIE

Sent Date: _____

Calculated Due Date: 23-Mar-2011

Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (R310) NEW PRODUCT;NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT CHEMIST

Ingredients: See page 3

R310
#27744

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 05-Oct-2010

Due Back: _____

DP Ingredient: See page 3

DP Title: #2517-RUE Companion Animal Safety Review

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #: _____

Assigned To

Date In

Date Out

Organization: RD / TRB

Last Possible Science Due Date: 21-Feb-2011

Team Name: TOX

Science Due Date: _____

Reviewer Name: _____

Sub Data Package Due Date: _____

Contractor Name: _____

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

Can be printed on its own page

*** Data Package Instructions ***

Attn TRB/TOX: Please conduct a companion animal safety review of the attached package in support of the proposed product. Contact Rosanna Louie-Juzwiak at 308.0037 with any questions.

Attachments:

- cover letter
- basic CSF
- draft label
- data matrix

MPID	MPID Status	Citation Reference	Guideline
43444905		Schwartz, E. (1994) Domestic Animal Safety Study of RM1601C Topical Spray (Frontline Spray Treatment) in Juvenile Dogs: Lab Project Number: 94423; PS-232DAS. Unpublished study prepared by White Eagle Toxicology Labs. 171 p.	
43121110		Arnaud, J.; Consalvi, P. (1993) Assessment of Tolerance of a 0.25% RM 1601 Spray Formulation in Dogs at 3, 9, and 15 ml/kg When Applied 6 times to the Haircoat at 28 Day Intervals: Revised: Lab Project Number CLI138. Unpublished study prepared by Rhone Merieux, Inc. 69 p.	
43121111		Arnaud, J.; Consalvi, P. (1993) Domestic Animal Safety: Assessment of the Tolerance of a 0.25% RM 1601 Spray in Nursing Puppies Administered Twice at a 28 Day Interval at a Dose Rate of 6 ml/kg: Revised: Lab Project Number CLI 180. Unpublished study prepared by Rhone Merieux, Inc. 32 p.	
46166108		Kuhn, J. (2003) Companion Animal Safety Study in Dogs: Cyphenothrin-IGR Spot-on for Dogs: Final Report. Project Number: 7650/03. Unpublished study prepared by Stillmeadow, Inc. and Miller, Thomas A. 53 p.	
43863802		Powell, L.; Paffett, R. (1995) Domestic Animal Safety Study by Topical Administration to Dogs: Fipronil Spot Treatment (RM 1601E): Lab Project Number: MRX 23/950406. Unpublished study prepared by Huntingdon Research Centre, Ltd. 219 p.	
47849609		Delport, P. (2009) Companion Animal Safety Evaluation on Dogs of Spot-On Products Containing Multiple Toxicants and Insect Growth Regulators: Final Report. Project Number: 2517FEGEN, CV/08/551. Unpublished study prepared by Clin Vet International. 129 p.	
43577711		Walker, K. (1995) Discussion in Support of Bridging Domestic Animal Safety Data on Frontline Spray Treatment to Frontline Spot Treatment Data Package. Unpublished study prepared by Rhone Merieux, Inc. 6 p.	
48129614		Hoskins, K. (2010) Companion Animal Safety for Sergeant's Fipronil + Cyphenothrin Squeeze-On for Dogs. Project Number: SERGEANTS/06/10/06. Unpublished study prepared by Sergeant's Pet Care Products, Inc. 39 p.	870.7200/Companion animal safety
43121111		Arnaud, J.; Consalvi, P. (1993) Domestic Animal Safety: Assessment of the Tolerance of a 0.25% RM 1601 Spray in Nursing Puppies Administered Twice at a 28 Day Interval at a Dose Rate of 6 ml/kg: Revised: Lab Project Number CLI 180. Unpublished study prepared by Rhone Merieux, Inc. 32 p.	870.7200/Companion animal safety
43121110		Arnaud, J.; Consalvi, P. (1993) Assessment of Tolerance of a 0.25% RM 1601 Spray Formulation in Dogs at 3, 9, and 15 ml/kg When Applied 6 times to the Haircoat at 28 Day Intervals: Revised: Lab Project Number CLI138. Unpublished study prepared by Rhone Merieux, Inc. 69 p.	870.7200/Companion animal safety
43444905		Schwartz, E. (1994) Domestic Animal Safety Study of RM1601C Topical Spray (Frontline Spray Treatment) in Juvenile Dogs: Lab Project Number: 94423; PS-232DAS. Unpublished study prepared by White Eagle Toxicology Labs. 171 p.	870.7200/Companion animal safety
43863802		Powell, L.; Paffett, R. (1995) Domestic Animal Safety Study by Topical Administration to Dogs: Fipronil Spot Treatment (RM 1601E): Lab Project Number: MRX 23/950406. Unpublished study prepared by Huntingdon Research Centre, Ltd. 219 p.	870.7200/Companion animal safety

JP#: (382790)

*** Product and Data Package Ingredients ***

Decision#: (438361)

PC Code	CAS	Ingredient Name
105402	65733-16-6	S-Methoprene
129013	39515-40-7	Cyphenothrin
129121	120068-37-3	Fipronil
129121	120068-37-3	Fipronil(9.8%)
105402	65733-16-6	S-Methoprene(8.8%)
129013	39515-40-7	Cyphenothrin(5%)

DATA PACKAGE BEAN SHEET

Date: 05-Oct-2010

Page 1 of 3

Decision #: 438361

DP #: (382789)

PRIA

Parent DP #:

Submission #: 880182

*** Registration Information ***

Registration: **2517-RUE - SERGEANT'S FIPRONIL + CYPHENOTHHRIN + METHOPREN**

Company: 2517 - SERGEANT'S PET CARE PRODUCTS, INC.

Risk Manager: RM 10 - Richard Gebken - (703) 305-6701 Room# PY1 S-7237

Risk Manager Reviewer: Rosanna Louie RLOUIE

Sent Date:

Calculated Due Date: 23-Mar-2011

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (R310) NEW PRODUCT;NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT CHEMIST

Ingredients: See page 3

R310
~~11/27/10~~
#2741

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 05-Oct-2010

Due Back:

DP Ingredient: See page 3

DP Title: #2517-RUE Acute Toxicity Review

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #: _____

Assigned To _____

Date In _____

Date Out _____

Organization: RD / TRB

Last Possible Science Due Date: 21-Feb-2011

Team Name: TOX

Science Due Date: _____

Reviewer Name: _____

Sub Data Package Due Date: _____

Contractor Name: _____

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

Can be printed on its own page

*** Data Package Instructions ***

Attn TRB/TOX: Please conduct an acute toxicity review of the attached package in support of the proposed product. Contact Rosanna Louie-Juzwiak at 308.0037 with any questions.

Attachments:

- cover letter
- basic CSF
- draft label
- data matrix

MRID	MRID Status	Citation Reference	Guideline
48129604		Leoni, A. (2010) Acute Dermal Toxicity (Limit Test) with Dog Products (in Rats): Final Report. Project Number: 100138B. Unpublished study prepared by BSL Bioservice Scientific Laboratories GmbH. 34 p.	870.1000/Acute Toxicity testing - background
48129603		Leoni, A. (2010) Acute Oral Toxicity Up and Down Procedure with Dog Products (in Rats): Final Report. Project Number: 100137B. Unpublished study prepared by BSL Bioservice Scientific Laboratories GmbH. 45 p.	870.1100/Acute Oral Toxicity
48129608		Stelter, D. (2010) Test for Sensitization (Guinea Pig Maximisation Test) with Dog Products (in Guinea Pigs): Final Report. Project Number: 100141B. Unpublished study prepared by BSL Bioservice Scientific Laboratories GmbH. 41 p.	870.2600/Skin sensitization
48129606		Ahuja, V. (2010) Acute Eye Irritation/Corrosion with Dog Products (in Rabbits): Final Report. Project Number: 100140B. Unpublished study prepared by BSL Bioservice Scientific Laboratories GmbH. 33 p.	870.2400/Acute eye irritation
48129607		Ahuja, V. (2010) Acute Dermal Irritation/Corrosion with Dog Products (in Rabbits): Final Report. Project Number: 100139B. Unpublished study prepared by BSL Bioservice Scientific Laboratories GmbH. 29 p.	870.2500/Acute dermal irritation
48129604		Leoni, A. (2010) Acute Dermal Toxicity (Limit Test) with Dog Products (in Rats): Final Report. Project Number: 100138B. Unpublished study prepared by BSL Bioservice Scientific Laboratories GmbH. 34 p.	870.1200/Acute dermal toxicity
48129605		Hoskins, K. (2010) Waiver Request of Requirement for Further Testing for Acute Inhalation Toxicity for Following Sergeant's Products: Sergeant's Fipronil + Cyphenothrin Squeeze-On for Dogs, Sergeant's Fipronil + Cyphenothrin + Methoprene Squeeze-On for Dogs, Sergeant's Fipronil + Cyphenothrin + Nylar Squeeze-On for Dogs, Sergeant's Fipronil + Nylar Squeeze-On for Dogs, Sergeant's Fipronil + Etofenprox Spot-On for Cats, Sergeant's Fipronil + Etofenprox + Methoprene Spot-On for Cats, Sergeant's Fipronil + Etofenprox + Nylar Spot-On for Cats, Sergeant's Fipronil + Nylar Spot-On for Cats. Project Number: SERGEANTS/06/10/05. Unpublished study prepared by Sergeant's Pet Care Products, Inc. 6 p.	870.1300/Acute inhalation toxicity

DP#: (382789)

*** Product and Data Package Ingredients ***

Decision#: (438361)

PC Code	CAS	Ingredient Name
105402	65733-16-6	S-Methoprene
129013	39515-40-7	Cyphenothrin
129121	120068-37-3	Fipronil
129121	120068-37-3	Fipronil(9.8%)
105402	65733-16-6	S-Methoprene(8.8%)
129013	39515-40-7	Cyphenothrin(5%)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

February 15, 2011

MEMORANDUM

Subject: Name of Pesticide Product: SERGEANT'S FIPRONIL + CYPHENOTHHRIN
+ METHOPRENE SQUEEZE-ON FOR DOGS
EPA Reg. No. /File Symbol: 2517-RUE
DP Barcodes: DP 382789, 382790
Decision No.: 438361
Action Code: R310
PC Codes: 129121 (Fipronil: 9.8%)
129013 (Cyphenothrin: 5.0%)
105402 (S-Methoprene: 8.8%)

From: Byron T. Backus, Ph.D., Toxicologist
Technical Review Branch
Registration Division (7505P)

Byron T. Backus
Feb -15 - 2011
Hershman

To: Rosanna Loie-Juzwiak/Richard Gebken RM 10
Insecticide Branch
Registration Division (7505P)

Registrant: SERGEANT'S PET CARE PRODUCTS, INC.

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>by wt.</u>
129121 Fipronil	9.8%
129013 Cyphenothrin	5.0%
105402 (S)-methoprene	8.8%
<u>Other Ingredient(s):</u>	<u>76.4%</u>
TOTAL	100.0%

ACTION REQUESTED: The Risk Manager requests:

For DP 382789: "...Please conduct an acute toxicity review of the attached package in support of the proposed product..."

For DP 382790: "...Please conduct a companion animal safety review of the attached package in support of the proposed product..."

BACKGROUND:

The material received for review includes a data matrix, a CSF (dated 8/11/2010) and a proposed label for this product, indicating use on adult dogs and puppies 12 weeks old and older.

COMMENTS AND RECOMMENDATIONS:

1. The five cited acute toxicity studies (48129603, 48129604, 48129606 – 48129608) were conducted on a formulation containing as active ingredients: Fipronil (9.8%), (S)-Methoprene (8.5%), Cyphenothrin (5.5%) and Pyriproxyfen (2%). The studies were previously classified as acceptable (TRB memorandum dated November 23, 2010 for 2517-RUN), and can be used to support the registration of 2517-RUE. The signal word is WARNING, based on the eye irritation potential (MRID 48129606).
2. The material in the inhalation waiver request in MRID 48129605 is applicable to 2517-RUE. Refer to the TRB memorandum dated November 23, 2010 for 2517-RUN which states: "Based on the amount of formulation applied (0.5-4.5 mL), the packaging of these products (single-use containers or ampoules), the non-volatile nature of the formulations, and the application method (directly to the skin of the dog or cat) which does not result in any respirable particles, TRB concludes that a waiver for the acute inhalation study requirement is appropriate, and that these products can be assigned to EPA Toxicity Category IV by this exposure route."
3. The proposed label dosage rates for 2517-RUE are 0.67 mL for dogs up to 22 lbs; 1.34 mL for dogs 23-44 lbs; 2.68 mL for dogs 45-88 lbs; and 4.02 mL for dogs 89-132 lbs. The cited companion animal safety studies include MRID 47849609, in which six Group A2 puppies were treated with 5 applications of substance IA (containing 8.2% cyphenothrin and 9.8% fipronil) and 5 applications of substance II (55.16% etofenprox, 8.78% methoprene and 2.31% pyriproxyfen). The mean total dose was 1.84 (range: 1.79-1.88) mL/kg for test substance IA and 6.88 (range: 6.69-7.05) mL/kg for substance II. Group B2 adults were treated with 5 applications of substance IA and 5 applications of substance III (8.90% methoprene, 2.43% pyriproxyfen). The mean total dose was 0.395 (range: 0.352-0.443) mL/kg for substance IA and 0.395 (range: 0.352-0.443) mL/kg for substance III. The proposed label dosage rates for 2517-RUE are 0.67 mL for dogs up to 22 lbs; 1.34 mL for dogs 23-44 lbs; 2.68 mL for dogs 45-88 lbs; and 4.02 mL for dogs 89-132 lbs. Assuming that the test substances and proposed product have a specific gravity = 1.0, the puppies were treated with means of 151 mg cyphenothrin/kg, 180 mg fipronil/kg, and 604 mg methoprene/kg. Dividing these values by 5 would give 30.2 mg cyphenothrin/kg, 36 mg fipronil/kg and 120.8 mg methoprene/kg. In terms of the formulation for 2517-RUE these values would be 0.604, 0.367, and 13.73 mL/kg, respectively, indicating that 0.67 mL would be acceptable for puppies weighing 1.83 (0.67 mL divided by 0.367 mL/kg) kg or more. 1.83 kg is 4.03 lb, so (applying a 5X safety factor) we can accept the data for dogs weighing 4 pounds or more. The cited companion animal safety studies adequately support the use of this product on dogs and puppies 12 weeks old or older. **Labeling should indicate a minimum weight of 4 lbs for dogs or puppies.**

4. The following is the acute toxicity profile for Sergeant's Fipronil + Cyphenothrin + Methoprene Squeeze-On for Dogs (EPA File Symbol 2517-RUF), based on the results of the acute toxicity studies:

Acute oral toxicity	III	Cited	MRID 48129603
Acute dermal toxicity	III	Cited	MRID 48129604
Acute inhalation toxicity	(IV)	Waived	(MRID 48129605)
Primary eye irritation	II	Cited	MRID 48129606
Primary dermal irritation	IV	Cited	MRID 48129607
Dermal sensitization	Positive	Cited	MRID 48129608

5. Based on the acute toxicity profile above, and taking into consideration the proposed uses specified on the label and information in the CSF, the following would be the precautionary and first aid labeling for EPA File Symbol 2517-RUN [Sergeant's Fipronil + Cyphenothrin Squeeze-On for Dogs] as obtained from the Label Review System:

PRODUCT ID #: 002517-00142

PRODUCT NAME: SERGEANT'S FIPRONIL + CYPHENOTHHRIN SQUEEZE-ON FOR DOGS

PRECAUTIONARY STATEMENTS

SIGNAL WORD: WARNING

Hazards to Humans and Domestic Animals:

Restricted Use Pesticide due to toxicity categories. For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification. Child Resistant Packaging Required.

Causes substantial but temporary eye injury. Harmful if absorbed through skin. Harmful if swallowed. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses). Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse. Avoid contact with skin. Wear long-sleeved shirt and long pants, socks, shoes, and gloves.

Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

First Aid:

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

If on skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.

- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

NOTE TO PHYSICIAN: Note to PM/CRM/Registrant: The proposed label should contain a "Note to Physician". The following statements are suggested types of information that may be included, if applicable: - technical information on symptomatology; - use of supportive treatments to maintain life functions; - medicine that will counteract the specific physiological effects of the pesticide; - company telephone number to specific medical personnel who can provide specialized medical advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

According to the LRS, this product is a candidate for restricted use because it is in Toxicity Category II for eye exposure. However, TRB concludes that, based on the packaging (in ampules) and proposed product use (direct application to the skin of dogs or cats), the risk of eye exposure is adequately reduced, and a restricted use classification is not necessary.

6. The CSF (dated 8/11/2010) for 2517-RUE should also be reviewed and accepted by the TRB Chemistry Team.

DATA PACKAGE BEAN SHEET

Date: 05-Oct-2010

Page 1 of 3

Decision #: 438361

DP #: (382791)

PRIA

Parent DP #:

Submission #: 880182

*** Registration Information ***

Registration: 2517-RUE - SERGEANT'S FIPRONIL + CYPHENOTHHRIN + METHOPREN

Company: 2517 - SERGEANT'S PET CARE PRODUCTS, INC.

Risk Manager: RM 10 - Richard Gebken - (703) 305-6701 Room# PY1 S-7237

Risk Manager Reviewer: Rosanna Louie RLOUIE

Sent Date:

Calculated Due Date: 23-Mar-2011

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (R310) NEW PRODUCT;NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT CHEMIST

Ingredients: See page 3

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 05-Oct-2010

Due Back:

DP Ingredient: See page 3

DP Title: #2517-RUE: CRP Review

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: RD / TRB

10/5/10

12/23/10

Last Possible Science Due Date: 21-Feb-2011

Team Name: Child Resistant Packaging

Science Due Date:

Reviewer Name:

Sub Data Package Due Date:

Contractor Name:

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

Can be printed on its own page

*** Data Package Instructions ***

Attn TRB/CRP: Please conduct a CRP Packaging review of the attached package in support of the proposed product. Contact Rosanna Louie-Juzwiak at 308.0037 with any questions.

Attachments:

- cover letter
- letter for CRP certification (including cited studies)
- letter for CRP information
- basic CSF
- draft label
- data matrix

NOTE: with regards to CRP review, there is no greater toxicity from cyphenothrin or s-methoprene exposure (i.e., does not trigger need for CRP) that would exceed that of fipronil.

DP#: (382791)

*** Studies Sent for Review ***

Decision#: (43836 t)

MRID	MRID Status	Citation References	Guideline
48059803		Ward, R. (2010) Evaluation of the Dog Squeeze on 0.67ml White Applicator with Orange Label Indicator (3x), Scissors to Open - F=1 as a Poison Prevention Package for Sergeant's Pet Care Products, Inc.: Final Report. Project Number: 1746/002. Unpublished study prepared by Perritt Laboratories, Inc. 28 p.	
48059804		Ward, R. (2010) Evaluation of the Dog Squeeze on 1.34ml White Applicator with Green Label Indicator (3x), Scissors to Open - F=t as a Poison Prevention Package for Sergeant's Pet Care Products, Inc.: Final Report. Project Number: 1746/003. Unpublished study prepared by Perritt Laboratories, Inc. 28 p.	
48059805		Ward, R. (2010) Evaluation of the Dog Squeeze on 2.68ml White Applicator with Red Label Indicator (3x), Scissors to Open - F=1 as a Poison Prevention Package for Sergeant's Pet Care Products, Inc.: Final Report. Project Number: 1746/004. Unpublished study prepared by Perritt Laboratories, Inc. 28 p.	
48059806		Ward, R. (2010) Evaluation of the Dog Squeeze on 4.02ml White Applicator with Blue Label Indicator (3x), Scissors to Open - F=t as a Poison Prevention Package for Sergeant's Pet Care Products, Inc.: Final Report. Project Number: 1746/005. Unpublished study prepared by Perritt Laboratories, Inc. 28 p.	

DP#: (382791)

*** Product and Data Package Ingredients ***

Decision#: (438361)

PC Code	CAS	Ingredient Name
105402	65733-16-6	S-Methoprene
129013	39515-40-7	Cyphenothrin
129121	120068-37-3	Fipronil
129121	120068-37-3	Fipronil(9.8%)
105402	65733-16-6	S-Methoprene(8.8%)
129013	39515-40-7	Cyphenothrin(5%)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

December 23, 2010

NOTE TO RM 10 Rosanna Louie-Juzwiak

SUBJECT: Certification to Compliance with Child-Resistant Packaging Regulations
EPA FILE NO: 2517-RUE, DP 382791, Decision # 438361

The August 11, 2010 CRP certification and bridging letter (indicating the same size and color package as package tested) for EPA Registration No. 2517-RUE **are acceptable**. The August 11, 2010 label for EPA Registration No. 2517-RUE has the **same CRP directions as were used in the CRP testing**.

All the requirements for CRP have been met for EPA Registration No. 2517-RUE. The directions on opening the package given to consumers must be identical to those given to the seniors during testing.

Should any human experience/epidemiological evidence indicate a problem once the product is in the marketplace, the Agency reserves the right to reexamine this data comprehensively and to question the child resistance of the package involved.

Thank you for your cooperation in this matter. If you have any questions please contact me at (703)-308-7368.

A handwritten signature in cursive script, reading "Rosalind L. Gross", is positioned above the typed name.

Rosalind L. Gross



Sergeant's Pet Care Products, Inc.

2625 South 158th Plaza • Omaha, NE 68130-1770 • Telephone 402.938.7000 • Fax 402.938.7091 • www.sergeants.com

OK RLG

August 11, 2010

Richard Gebken, PM10
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Document Processing Desk
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject: Child Resistant Packaging Certification
Sergeant's Fipronil + Cyphenothrin + Methoprene Squeeze-On for Dogs
EPA File Symbol 2517-NEW RVE

Dear Mr. Gebken:

I certify that the packaging used for the following product meets the standards of 40 CFR 157.32, including the revised standards in 16 CFR 1700.15(b), when tested by the revised testing procedures in 16 CFR 1700.20, as published in 60 FR 37710 (July 21, 1995):

- Sergeant's Fipronil + Cyphenothrin + Methoprene Squeeze-On for Dogs (EPA File Symbol 2517-NEW) RVE

Sergeant's Pet Care Products, Inc. (Sergeant's, 2625 South 158th Plaza, Omaha, NE 68130-1770, EPA Company Number 2517) is submitting this child resistant packaging certification to support for the new end-use product for Sergeant's Fipronil + Cyphenothrin + Methoprene Squeeze-On for Dogs (EPA File Symbol 2517-NEW). All product labels have language specifying the use of scissors to open the product container and label language stating the product is not to be applied by children.

If you have any questions, please contact me at 402-938-7079.

Sincerely,

Kelly R. Hoskins / ZAT

Kelly R. Hoskins
Manager of Technical Affairs

cc: Larry Nouvel



Sergeant's Pet Care Products, Inc.

2626 South 158th Plaza • Omaha, NE 68130-1770 • Telephone 402.938.7000 • Fax 402.938.7091 • www.sergeants.com

August 11, 2010

o/c
RLG

Rosalind Gross
c/o Richard Gebken
Registration Division
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Document Processing Desk
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject: Child Resistant Packaging Support
Sergeant's Fipronil + Cyphenothrin + Methoprene Squeeze-On for Dogs (EPA
File Symbol: 2517-NEW) RLG

Dear Ms. Gross:

Sergeant's Pet Care Products, Inc. (EPA Company Number 2517) is submitting a request to rely on previously submitted Child Resistant Packaging (CRP) studies to support this new registration. The CRP data were submitted to EPA on April 12, 2010 in support of the pending registration applications under EPA File Symbols: 2517-RGT, 2517-RGA, 2517-RGL, and 2517-RGU (all of which contain Fipronil at 9.7-9.8%).

Sergeant's generated CRP data on a standard white applicator in sizes 0.5, 0.67, 1.34, 2.68, and 4.02 mL. The following is a summary table of the applicators that were tested and submitted to EPA in the CRP data:

Use	Applicator Base Color	Fill Weight (mL)	Color
Dog Up to 22 lbs	White	0.67	Orange ✓
Dog 23-44 lbs	White	1.34	Green ✓
Dog 45-88 lbs	White	2.68	Red ✓
Dog 89-132 lbs	White	4.02	Blue ✓
Cats All Weights	White	0.50	Purple ✓

CRP data is required for this new product because of the inclusion of the active ingredient fipronil (9.8%) in the pet squeeze-on product. The CRP testing was conducted on a standard package size and color configuration for a product containing fipronil (9.8%). The Sergeant's Fipronil + Cyphenothrin + Methoprene Squeeze-On for Dogs product being submitted today also contains fipronil at 9.8%. Additionally, Sergeant's already has dog squeeze-on products approved by EPA containing 20-30% cyphenothrin (EPA Registration Numbers 2517-127 through 2517-132) that are not subject to CRP. This new product contains 5% cyphenothrin and



Sergeant's Pet Care Products, Inc.

2625 South 158th Plaza • Omaha, NE 68130-1770 • Telephone 402.938.7000 • Fax 402.938.7091 • www.sergeants.com

8.8 % methoprene. Additionally, there are EPA registered products containing s-methoprene, none of which are subject to CRP.

Furthermore, Sergeant's does not anticipate any additional toxicity through the combination of fipronil, cyphenothrin and methoprene. When Sergeant's Fipronil + Cyphenothrin + Methoprene Squeeze-On for Dogs is marketed, it will have the same applicator color (white) and fill weight colors per mL fill weight as was used in the submitted and referenced CRP testing. Based on available information, the density range of the pending products on which the CRP data were generated is the same as the new product (1.0-1.5 g/cc). Therefore, Sergeant's is relying on MRID's: 48059803, 48059804, 48059805, and 48059806 to fulfill the CRP data requirements for Sergeant's Fipronil + Cyphenothrin + Methoprene Squeeze-On for Dogs.

If you have any questions, please contact me at 402-938-7079.

Sincerely,

Kelly R. Hoskins /ZAT

Kelly R. Hoskins
Manager of Technical Affairs

cc: Larry Nouvel

DATA PACKAGE BEAN SHEET

Date: 05-Oct-2010

Page 1 of 3

Decision #: 438361

DP #: (382792)

PRIA

Parent DP #:

Submission #: 880182

*** Registration Information ***

Registration: **2517-RUE - SERGEANT'S FIPRONIL + CYPHENOTHHRIN + METHOPREN**

Company: 2517 - SERGEANT'S PET CARE PRODUCTS, INC.

Risk Manager: RM 10 - Richard Gebken - (703) 305-6701 Room# PY1 S-7237

Risk Manager Reviewer: Rosanna Louie RLOUIE

Sent Date:

Calculated Due Date: 23-Mar-2011

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (R310) NEW PRODUCT;NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT CHEMIST

Ingredients: See page 3

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 05-Oct-2010

Due Back:

DP Ingredient: See page 3

DP Title: #2517-RUE: Efficacy Review

CSF Included: ☐ Yes ☒ No

Label Included: ☒ Yes ☐ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: RD / TRB

Last Possible Science Due Date: 21-Feb-2011

Team Name: Efficacy (IB)

Science Due Date:

Reviewer Name:

Sub Data Package Due Date:

Contractor Name:

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

Can be printed on its own page

*** Data Package Instructions ***

Attn Efficacy Reviewer: Please conduct an efficacy review of the attached package in support of the proposed product. Contact Rosanna Louie-Juzwiak at 308.0037 with any questions.

Attachments:

- cover letter
- draft label
- data matrix

1126-10

MRID	MRID Status	Citation Reference	Guideline
45620501		Pengo, G.; Polmeier, M.; Barrick, R. (2000) An Efficacy Study of Frontline Spray, Frontline Top Spot, and ML-2,095,988 509T, for the Treatment and Control of Trichodectes canis in the Dog: Final Report: Lab Project Number: PR&D 0022101, PR&D 00221. Unpublished study prepared by Centro Veterinario Oriolo. 24 p. {OPPTS 810.3300}	
43121114		Everett, R.; Cunningham, J. (1993) A Dose Titration Study to Determine the Optimal Spray Concentration of RM 1601 for Long Term Control of the Cat Flea Ctenocephalides felis and the Brown Dog Tick Rhipicephalus sanguineus in the Dog: Revised: Lab Project Number: RMD 292: P/214LT. Unpublished study prepared by Agresearch Consultants. 53 p.	
45612701		Ahmed, Z. (2002) Study Summaries: Frontline Plus For Dogs. Unpublished study prepared by Merial. 40 p.	
46298501		Miller, T. (2003) Effect of Shampoo After Treatment with Cyphenothrin Squeeze-on on Efficacy against Adult Cat Fleas (Ctenocephalides felis), Adult Brown Ticks (Rhipicephalus sanguineus) on Dogs: Analysis of Data and Conclusions. Project Number: MS/20D. Unpublished study prepared by Sharp Veterinary Hospital and Vetoquinol N.A., Inc. 15 p.	810.3300/Treatments to control pests of humans and pets
43121115		Cruthers, L. (1993) Product Performance: A Dose Confirmation Study to Verify the Optimal Spray Concentration of RM 1601 for Long Residual Control of the Cat Flea (Ctenocephalides felis) and the Brown Dog Tick (Rhipicephalus sanguineus) in the Dog: Revised: Lab Project Number: 9251: P/215LT. Unpublished study prepared by Professional Labs and Research Services, Inc. 51 p.	
43121116		Everett, R.; Cunningham, J. (1993) A Comparative Evaluation of Two Treatment Regimes Using RM 1601 Spray for Control of the Cat Flea Ctenocephalides felis on the Dog: Revised: Lab Project Number: RMD 692: P/222LT. Unpublished study prepared by Agresearch Consultants, Inc. 40 p.	
48129610		Sharp, M. (2009) Immediate Efficacy of a Combined Application of Frontline Plus with Cyphenothrin as a Squeeze-On Against Fleas (Ctenocephalides felis) and Ticks (Rhipicephalus sanguineus) on Dogs: Analyses of Data Conclusions. Project Number: MS/164/D. Unpublished study prepared by Sharp Veterinary Research. 24 p.	810.3300/Treatments to control pests of humans and pets
43121117		McCall, J.; McTier, T. (1993) Laboratory Evaluation of RM 1601 Spray for Control Demacantor variabilis and Rhipicephalus sanguineus on the Dog: Lab Project Number: RM/TKS/93/1L: PS/229LT. Unpublished study prepared by TRS Labs, Inc. 18 p.	
45620505		Gaxiola, S.; Alva, R.; Irwin, J. (2001) PR & D 0052301: Frontline Spray/Frontline Spot-On/ML-2, 095, 988 509T/Dogs/Solution/Topical: Final Report: Lab Project Number: PR&D 0052301, PR&D 00523. Unpublished study prepared by University of Sinaloa. 40 p. {OPPTS 810.3300}	
48189203		Miller, T. (2009) Dose Titration with S-Methoprene Squeeze-On on Dogs Measuring Flea Egg Sterilization: Analyses of Data and Conclusions. Project Number: MS/172D. Unpublished study prepared by Sharp Veterinary Research. 42 p.	810.3300/Treatments to control pests of humans and pets
48129611		Sharp, M. (2010) Immediate Efficacy Following Application of Frontline with Cyphenothrin Squeeze-On Against Fleas (Ctenocephalides felis) and Ticks (Rhipicephalus sanguineus) on Dogs: Analyses of Data Conclusions. Project Number: MS/183D. Unpublished study prepared by Sharp Veterinary Research. 29 p.	810.3300/Treatments to control pests of humans and pets
43121118		Everett, R.; Cunningham, J. (1993) An Investigation Study to Evaluate the Effect of Bathing of Laboratory Dogs on the Efficacy of RM1601 Spray: Revised: Lab Project Number: RMD 592: P/220LT. Unpublished study prepared by Agresearch Consultants, Inc. 43 p.	
45620504		Marchiondo, A. (2001) PR & D 0024101: Frontline Spray/Frontline Spot-On/ML-2, 095, 988 509T/Dogs/Solution/Topical: Final Report: Lab Project Number: PR&D 0024101: PR&D 00241. Unpublished study prepared by Stillmeadow, Inc. 29 p. {OPPTS 810.3300}	
45866902		McCall, J.; Alva, R.; Irwin, J.; et al. (2002) A Study to Evaluate the Efficacy of Frontline Plus for Control of Mosquitoes, Aedes aegypti, on Dogs: Final Report: Lab Project Number: PR&D 0055201. Unpublished study prepared by TRS Labs, Inc. 24 p. {OPPTS 810.3300}	

DP#: (382792)

*** Product and Data Package Ingredients ***

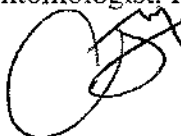
Decision#: (438361)

PC Code	CAS	Ingredient Name
105402	65733-16-6	S-Methoprene
129013	39515-40-7	Cyphenothrin
129121	120068-37-3	Fipronil
129121	120068-37-3	Fipronil(9.8%)
105402	65733-16-6	S-Methoprene(8.8%)
129013	39515-40-7	Cyphenothrin(5%)

Efficacy Review

Date: December 6, 2010

Efficacy Reviewer: Clayton Myers, Ph.D., Entomologist, RD-IB
myers.clayton@epa.gov
703-347-8874

 12-6-10

Risk Manager Rev.: Rosanna Louie

Products: Sergeant's Fipronil + Cyphenothrin + Methoprene Squeeze-on for Dogs

EPA Reg. #: 2517-RUE

A.I.'s: Fipronil (9.8%), Cyphenothrin (5.0%), S-Methoprene (8.8%)

Decision #s: 438361

DP #s: 382792

Submission: R310, New Products, RD Science Review

MRIDs: Submitted: 48129609, 48129610, 48129611, 48129612, 48129613,
48189203

Cited: 43121114, 43121115, 43121116, 43121117, 43121118,
43121122, 43577712, 45612701, 45620501, 45620504,
45620505, 45620506, 45628201, 45866902, 46298501

GLP: No

MRID 48129609

Title: Overview and Summary of Fipronil/Cyphenothrin Dog Efficacy for Sergeant's Fipronil + Cyphenothrin Squeeze-On for Dogs (Overview of other submissions).

Guideline: OPPTS 810.3300

Study Summary of the Results:

This submission is an overall summary and clarification of the other submitted MRIDs associated with this application

Entomologist's Observations/Discussion:

Supplementary Information

MRID 48129810

Title: Immediate Efficacy of a Combined Application of Frontline Plus with Cyphenothrin as a Squeeze-on against Fleas (*Ctenocephalis felis*) and Ticks (*Rhipicephalus sanguineus*) on Dogs.

Guideline: OPPTS 810.3300

Materials and Methods: Cyphenothrin was added to Frontline plus at 3 rates (5%, 10%, and 15%) for efficacy evaluations. Dose volumes applied were based on the Frontline label, but dilution was not taken into account for the existing fipronil, therefore fipronil dosage was slightly lower than that of Frontline alone. 18 dogs were allocated to 6 groups of 3 dogs each. Group 1, untreated control; Group 2, Frontline alone, Groups 3-5 Frontline plus cyphenothrin at described rates. Dogs were infested with 100 fleas and 50 ticks one day before treatment, and again at 7 and 14 days after treatment. Counts were made at 1 and 4 hours post treatment and also on day 14 at 1 and 4 hours post placement—this was to measure speed of kill and/or repellency. Counts were also made at 24 and 48 hours after initial infestation and all re-infestations. Parasites were not removed until the final count. Mortality was calculated using Abbott's formula. For speed of kill/repellence, the number of killed/repelled fleas on the liner below each treated dog was divided by the total number of fleas placed on the dog (all x 100), adjusted for 'normal' attrition on control dogs.

Study Summary of the Results:

1. Mean efficacy against fleas and ticks exceeded 90% when assessed at 1-2 days after treatment or reinfestation with parasites, through 14 days after treatment.
2. Immediate efficacy on fleas (i.e. kill/repellence within 4 hours of treatment) ranged from 9-74% for 1-4 hours immediately after treatment. With reinfestations after 14 days from treatment, efficacy exceeded 99% within 4 hours for all treatments that included cyphenothrin.
3. Immediate efficacy on ticks ranged from 2-64% for 1-2 hours immediately after treatment. With reinfestations after 14 days from treatment, efficacy exceeded 95% within 1 hour, for the lowest percentage of cyphenothrin treatment, and exceeded 84% for all treatments.

Entomologist's Observations/Dicussion:

1. Efficacy against fleas and ticks was adequate to support controls claims through 14 days after treatment.
2. While immediate efficacy against fleas and ticks was enhanced when assessed at 1 and 4 hours after treatment (or reinfestation), the immediate efficacy did not exceed 90% with any consistency for the treatments evaluated immediately after treatment. However, after 14 days, this immediate efficacy was observed for reinfestations of both fleas and ticks. This is likely due to the more complete spread of the spot-on material throughout the animal coat at 14 days. Claims for killing (or 'starts killing') within hours would be supported by this data, but not immediately after treatment of the animals.

MRID 48129811

Title: Immediate Efficacy Following Application of Frontline with Cyphenothrin Squeeze-on against Fleas (*Ctenocephalis felis*) and Ticks (*Rhipicephalus sanguineus*) on Dogs.

Guideline: OPPTS 810.3300

Materials and Methods: Cyphenothrin was added to Frontline plus at the rate of approximately 5% (4.76% cyphenothrin) for efficacy evaluations. Dose volumes applied were based on the Frontline label, but dilution was not taken into account for the existing fipronil, therefore fipronil dosage was slightly lower than that of Frontline alone. 18 dogs were allocated to 3 groups of 6 dogs each. Group 1, untreated control; Group 2, Frontline+cyphenothrin, Groups 3, Frontline alone.. Dogs were infested with 100 fleas and 50 ticks one day before treatment, and again at 7, 14, 21, and 28 days after treatment. Counts were made at 1 and 4 hours post treatment and also after every reinfestation—this was to measure speed of kill and/or repellency. Counts were also made at 24 and 48 hours after initial infestation and all re-infestations. Parasites were not removed until the final count. Mortality was calculated using Abbott's formula. For speed of kill/repellence, the number of killed/repelled fleas on the liner below each treated dog was divided by the total number of fleas placed on the dog (all x 100), adjusted for 'normal' attrition on control dogs.

Study Summary of the Results:

1. Mean efficacy against fleas and ticks exceeded 90% when assessed at 1-2 days after treatment or reinfestation with parasites, through 28 days after treatment.
2. Immediate efficacy on fleas (i.e. kill/repellence within 4 hours of treatment) ranged from 9-68% for 1-4 hours immediately after treatment. With reinfestations after 7, 14, 21, and 28 days from treatment, efficacy exceeded 90% within 4 hours for all treatments that included cyphenothrin, but did not exceed 90% within 1 hour after reinfestation.
3. Immediate efficacy on ticks ranged from 5-75% for 1-2 hours immediately after treatment. With reinfestations after 7, 14, 21, and 28 days from treatment, efficacy exceeded 90% within 4 hours for all dates. For 21 and 28 days from treatment, adequate efficacy was observed within 1 hour of reinfestation.

Entomologist's Observations/Dicussion:

1. Efficacy against fleas and ticks was adequate to support controls claims through 28 days (one month) after treatment.
2. While immediate efficacy against fleas and ticks was marginally enhanced when assessed at 1 and 4 hours after treatment (or reinfestation), the immediate efficacy did not exceed 90% with any consistency for the treatments evaluated immediately after treatment. However, after 7 days, this immediate efficacy was observed for reinfestations of both fleas and ticks. This is likely due to the more complete spread of the spot-on material throughout the animal coat at 7+ days. Claims for killing (or

'starts killing') within hours would be supported by this data, but not immediately after treatment of the animals.

MRID 48129812

Title: Immediate Efficacy Following Application of Frontline Plus with Cyphenothrin Squeeze-on against Fleas (*Ctenocephalis felis*) and Ticks (*Rhipicephalus sanguineus*) on Dogs.

Guideline: OPPTS 810.3300

Materials and Methods: Cyphenothrin was added to Frontline plus at the rate of approximately 5% (4.76% cyphenothrin) for efficacy evaluations. Dose volumes applied were based on the Frontline label, but dilution was not taken into account for the existing fipronil, therefore fipronil dosage was slightly lower than that of Frontline alone. 18 dogs were allocated to 3 groups of 6 dogs each. Group 1, untreated control; Group 2, Frontline+cyphenothrin, Groups 3, Frontline alone.. Dogs were infested with 100 fleas and 50 ticks one day before treatment, and again at 7, 14, 21, 28, and 35 days after treatment. Counts were made at 1 and 4 hours post treatment and also after every reinfestation—this was to measure speed of kill and/or repellency. Counts were also made at 24 and 48 hours after initial infestation and all re-infestations. Parasites were not removed until the final count. Mortality was calculated using Abbott's formula. For speed of kill/repellence, the number of killed/repelled fleas on the liner below each treated dog was divided by the total number of fleas placed on the dog (all x 100), adjusted for 'normal' attrition on control dogs.

Study Summary of the Results:

1. Mean efficacy against fleas and ticks exceeded 90% when assessed at 1-2 days after treatment or reinfestation with parasites, through 35 days after treatment.
2. Immediate efficacy on fleas (i.e. kill/repellence within 4 hours of treatment) ranged from 0-75% for 1-4 hours immediately after treatment. With reinfestations after 7, 14, 21, 28, and 35 days from treatment, efficacy exceeded 90% within 4 hours for all only the 7 day reinfestation. Efficacy did not exceed 90% within 4 hours for reinfestations on days 14, 21, 28, or 35 days after treatment.
3. Immediate efficacy on ticks ranged from 11-71% for 1-4 hours immediately after treatment. With reinfestations after 7, 14, 21, and 28 days from treatment, efficacy exceeded 90% within 4 hours for only the 7 day reinfestation. Efficacy did not exceed 90% within 4 hours for reinfestations on days 14, 21, 28, or 35 days after treatment.

Entomologist's Observations/Dicussion:

1. Efficacy against fleas and ticks was adequate to support controls claims through 35 days (one month) after treatment.
2. While immediate efficacy against fleas and ticks was marginally enhanced when assessed at 1 and 4 hours after treatment (or reinfestation) compared to fipronil alone,

the immediate efficacy did not exceed 90% with any consistency for the treatments evaluated immediately 1-4 hours after initial treatment or reinfestation beyond 7 days after treatment. This data does not support any claims for faster kill or repellence due to the addition of cyphenothrin.

MRID 48129813

Title: Comparative efficacy evaluation of Sergeant's Squeeze-on and Frontline Plus for the treatment of adult cat flea (*Ctenocephalides felis*) and tick (*Haemaphysalis elliptica*, *Rhipicephalus sanguineus*, and *Dermacentor variabilis*) infestations on dogs.

Guideline: OPPTS 810.3300

Materials and Methods: Cyphenothrin was added to Sergeant's Fipronil-Methoprene formulation Frontline plus at the rate of approximately 5% for efficacy evaluations. This treatment was compared to fipronil-methoprene alone, and a positive control, Merial's Frontline Plus. Dose volumes applied were based on a titration by which dogs received 0.067 mL/kg body weight, to simulate the dosing at the high end of each respective weight class. Dogs were subgrouped by weight class with 6 dogs in each subclass (split over time to 3 dogs of each class in 2 consecutive studies). Group 1, untreated control; Group 2, Fipronil+Methoprene, Group 3, Fipronil+Methoprene+cyphenothrin, Group 4, Frontline Plus. Dogs were infested with 100 fleas and 50 ticks one day before treatment, and again at 7, 14, 21, and 28 days after treatment. Counts were made at 1 and 4 hours post treatment and also after every reinfestation—this was to measure speed of kill and/or repellency. Counts were also made at 24 and 48 hours after initial infestation and all re-infestations. Parasites were not removed until the final count. Mortality was calculated using Abbott's formula. For speed of kill/repellence, the number of killed/repelled fleas on the liner below each treated dog was divided by the total number of fleas placed on the dog (all x 100), adjusted for 'normal' attrition on control dogs.

Study Summary of the Results:

1. Mean efficacy against fleas exceeded 90% when assessed at 2 days after treatment or reinfestation with parasites, through 28 days after treatment.
2. Immediate group mean efficacy on ticks (all species) overall means were all below 90%.

Entomologist's Observations/Discussion:

1. Efficacy against fleas and ticks was adequate to support controls general claims through 35 days (one month) after treatment.
2. No immediate efficacy claims (i.e., within 1-4 hours of application or reinfestation by parasites) are supported by this data.

MRID 48189203

Title: Dose Titration with S-Methoprene Squeeze-Ons with Dogs Measuring Flea Egg Sterilization

Guideline: OPPTS 810.3300

Materials and Methods: 18 dogs were allocated to this study, with 6 in an untreated control group, and 2 each into 6 groups that received s-methoprene spot-on treatments at various dose rates based on weights of the 2 dogs, and designed to provide a range of dose rates from 3 mg/kg to 48 mg/kg. Dogs were infested with fleas 24 hours after treatment, and again weekly thereafter. Flea eggs were collected overnights from pans below each dog 1-2 times during the week after each re-infestation. Flea eggs were sorted into 2 aliquots of approximately 25 each—one incubated to measure fertility of the eggs, and the other incubated in a flea-growing medium to determine the number of fleas that developed from the eggs after 35 days. % hatch was calculated. % hatch reduction efficacy was calculated using Abbott's formula. Less than 90% on 2 or more successive collections was a criteria for treatment failure. Data was analyzed for correlation between dose and the duration of efficacy, to enable prediction of the duration of adequate efficacy at various doses.

Study Summary of the Results:

1. Application of the regression equation predicts residual efficacy in sterilizing female fleas and killing their eggs at a duration of 57 days for the largest heaviest dogs in the treatment regime to 122 days for the smallest dogs.
2. The adult emergence efficacy was terminated at 108 days with 100% efficacy for the five highest rates and >63 days for the lowest

Entomologist's Observations/Discussion

1. For the largest dogs (i.e., the lowest dosage of a.i. per kg dog weight), egg sterilization lasted 57 days and inhibition of adult emergence lasted 63 days. Therefore claims against flea eggs, larvae, and breaking of the flea life cycle is supported for 2 months (8 weeks). Claims must be revised to reflect this supported duration.

Overall Review of Label Claims and Directions:

Based upon submitted efficacy data, claims are supported for fleas and ticks through 35 days. Claims for immediate efficacy are not supported except to state "starts killing within hours" or "starts killing in as little as one hour". Repellence claims for fleas and ticks are not supported and must be removed from the label. Kill claims against flea eggs or larvae, are supported. Control claims against flea eggs or larvae, or claims against breaking the flea life cycle are supported for up to 2 months after treatment, however claims of 'up to 4 months' are acceptable, as this efficacy was supported for some dogs.

Line by Line Review of Label Efficacy Claims

Kills fleas (in as little as 1 hour), flea eggs, ticks (in as little as one hour), chewing lice & mosquitoes: Unacceptable unless revised to 'starts killing' for fleas and ticks.

Kills (and Repels) Fleas, Ticks, and Mosquitoes: Repels claim must be deleted.

Controls flea reinfestation for up to [16 weeks]: Acceptable

Fast Acting: Unacceptable

Kills ticks (in as little as 1 hour): Acceptable only if revised to say 'starts killing'

Kills ticks including those that may transmit Lyme disease: Acceptable

Dogs can be bathed 24 hours after treatment: Unacceptable

Waterproof: Acceptable

Long Lasting: Acceptable

Research demonstrates that [brand name] kills adult fleas (in as little as 1 hour), flea eggs, larvae and pupae for up to four months: Acceptable only if revised to 'starts' killing. Claim against 'pupae' must be deleted, as no data was submitted indicating the product kills flea pupae exposed to residue.

[brand name] prevents development of all flea stages for up to four months: Acceptable

Kills fleas (in as little as 1 hour), ticks (in as little as 1 hour), mosquitoes, (chewing) lice, flea eggs, larvae, and pupae: Acceptable only if kills claims are revised to 'starts killing'

Prevents all flea stages (adult fleas (in as little as 1 hour), flea eggs, flea pupae, and flea larvae): Acceptable except claim against 'pupae' must be deleted, as no data was submitted indicating the product kills flea pupae exposed to residue.

If dog is a high risk for flea re-infestation once a month application may be needed: Acceptable.

Once a month treatment is recommended: Acceptable.

A once monthly application is recommended for chewing lice: Acceptable.

Rapidly eliminates infestations with chewing lice: Acceptable.

Monthly flea, tick, mosquito, lice, and flea egg protection: Acceptable.

Monthly flea, tick, mosquito, and lice protection: Acceptable.

Kills flea eggs [larvae] [pupae] for up to 4 months: Acceptable except claim against 'pupae' must be deleted, as no data was submitted indicating the product kills flea pupae exposed to residue.

Aids in control of sarcoptic mange: Acceptable.

Kills fleas (in as little as 1 hour), ticks (in as little as 1 hour), mosquitoes, flea eggs, and lice: Acceptable only if kills claims are revised to 'starts killing'.

[Seven] [7] Way Protection! Kills fleas (in as little as 1 hour), ticks (in as little as 1 hour), mosquitoes, lice flea eggs, & flea larvae: '7-way' is an unacceptable nebulous claim. Kills claims must be revised to 'starts killing'

6 [Six] Way Protection! Kills fleas (in as little as 1 hour), ticks (in as little as 1 hour), mosquitoes, lice, flea eggs & flea larvae: '6-way' is an unacceptable nebulous claim. Kills claims must be revised to 'starts killing'

[4 Week] [Flea and Tick & Treatment]: Acceptable

Four (4) Week Flea, Tick, Mosquito and Lice Control: Acceptable

With (s)-methoprene Insect Growth Regulator which Breaks the Flea Life Cycle: Acceptable

With (s)-methoprene to Break Flea Life Cycle: Acceptable

With Insect Growth Regulator to Break Flea Life Cycle: Acceptable

Triple Action [!]: Fipronil and Cyphenothrin with (s)-methoprene IGR Effectively Breaks the Flea Life Cycle: Acceptable

Triple Action [!]: Effectively Breaks the Flea Life Cycle [!]: Acceptable

Best if used year round!: Acceptable

Kills & Repels Fleas (in as little as 1 hour) Up to [4 weeks]!: Kills must be revised to 'starts killing' and 'repels' claim must be deleted.

(ICON showing 4 week protection): Acceptable

4 Week Dose!: Acceptable

1 Month Dose!: Acceptable

Specially Formulated for Dogs and Puppies: Acceptable

Kills Flea Eggs & Flea Larvac for [(4 months)]!: Unacceptable unless revised to '2 months' or 'up to 4 months'.

Prevents Flea Eggs From Developing Into Biting Adults: Acceptable

Kills Ticks (in as little as 1 hour) for Up to [4 weeks]!: Acceptable only if revised to 'starts killing'.

Kills [all stages of] Deer Ticks (vector of Lyme Disease) for up to 4 weeks: Acceptable

Kills Ticks (in as little as 1 hour): Acceptable only if revised to 'starts killing'

Kills Ticks including Deer Ticks for up to 4 weeks: Acceptable

Kills Brown Dog Ticks (in as little as 1 hour): Acceptable only if revised to 'starts killing'

Kills [Brown], [American.] [and Lone Star] Dog Ticks for up to 4 weeks: Acceptable

Kills *Rhipicephalus sanguineus* for up to 4 weeks: Acceptable

When used monthly [brand name] completely breaks the flea life cycle and controls tick and chewing lice infestations: Acceptable

Kills American Dog Ticks [(*Dermacentor variabilis*)] for up to 4 weeks!: Acceptable

Apply once every [4 weeks]!: Acceptable

4 weeks Flea and Tick Treatment: Acceptable

Once A Month Flea and Tick Treatment: Acceptable

Kills & Repels Fleas (in as little as 1 hour) and Ticks (in as little as 1 hour) for up to 4 weeks!: Only acceptable if revised to starts killing, and also the repels claim must be deleted.

Kills all stages of the flea life cycle: Acceptable

Kills fleas (in as little as 1 hour). Ticks (in as little as 1 hour). Flea Eggs & Flea Larvac for up to 16 Weeks: Acceptable only if revised to 'starts killing'

Kills mosquitoes: Acceptable

Dogs can be bathed 24 hours after squeeze-on is applied: Unacceptable

Prevents and controls reinfestations: Unacceptable unless a pest and duration of control is associated (e.g., 'prevents and controls reinfestations of listed pests for 1 month [4 weeks]').

BACK/SIDE CARTON LABEL-MASTER LABEL

[brand name] contains Fipronil, cyphenothrin, and the insect growth regulator (IGR) (s)-methoprene to effectively kill [and repel] Fleas [(in as little as 1 hour)], Ticks [(in as little as 1 hour)], and kills mosquitoes and (chewing) lice. The active ingredients in [brand name] work by collecting in the hair follicles and skin oils. This product features a sustained-release formula that discharges from the animal's hair follicles using the natural skin oils, resulting in fast acting [and long lasting] control of Fleas and Ticks [(in as little as one hour)], [and kills mosquitoes] and chewing lice [for 30 days]. All repels claims must be removed from the label. All references to action in as little as 1 hour must be revised to 'starts acting' or 'starts killing' or alternatively, the claims of 'in little as 1 hour' can be removed. 'Fast acting' claim must be removed. The claims about movement in hair follicles is deferred to the RM Reviewer and PM.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

*File
2011*

October 4, 2010

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-438361
EPA File Symbol or Registration Number: 2517-RUE
Product Name: SERGEANT'S FIPRONIL + CYPHENOTHIRIN + METHIOPRENE SQUEEZE-
ON FOR DOGS
EPA Receipt Date: 11-Aug-2010
EPA Company Number: 2517
Company Name: SERGEANT'S PET CARE PRODUCTS, INC.

KELLY R. HOSKINS
SERGEANT'S PET CARE PRODUCTS, INC.
2625 SOUTH 158TH PLAZA
OMAHA, NE 68130-1703

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action previously identified as R320 has been reclassified as Action Code: R310

NEW PRODUCT;NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT
CHEMISTRY;ACUTE TOXICITY;PUBLIC HEALTH PEST EFFICACY);

The fee associated with this action is \$ 2,289 (50% of \$ 4,578). Payment of the amount of \$ 5,712 has been received. A refund in the amount of \$ 3,423 will be issued as soon as the action is completed.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

Front End Processing Staff
Information Technology & Resources Management Division

Memorandum

Date: 8 / 19 / 10

To: PM 10, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a: ☒ fully accepted submission
☐ partially accepted submission
☐ rejected submission

Completion of 21-Day Content Screen


PM- 10

EPA Reg. # (File Symbol) 2517-RUE

Decision # D

Data package delivered to
you on 8/19/10,
(date)

Jacket/Mini-jacket will be
transferred to you today.
(Pick up from Document Center)

Thank you, 

Registration Division's 21-Day Content Team

To the Document Center (ITRMD)

*Please transfer jacket/mini-jacket to the Product Manager Team circled below:

Minor Use Section: **PM -5**

Insecticide Branch: **PM -10** **PM-13**

Herbicide Branch: **PM-23** **PM-25**

Fungicide Branch: **PM-20** **PM-21** **PM-22**

Insect/Rodent Branch: **PM-1** **PM-7**

*Reminder to PM – If applicable, pick-up data from the Screening Room.

Processed by RD's Completeness Check Team

Steve Schaefer
(Team Member Signature)

8/19/10
(Date)

21-Day Screen Completed by
Contractor

21-Day Expires on 9-1-10

Jacket # 2517-RUE
MRID# 481892

Content Screen: Recommended to
Pass/Fail

86-5 Review: Passed/Failed/NA

Transfer This Jacket to:

STEPHEN SCHAIBLE

PM-10

PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

3/23/09

21 Day Screen Start Date: 8-11-10

Experts In-Processing Signature: M F Harrington Date 8-12-10 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>2517-RUE</u>		EPA Receipt Date: <u>8-11-10</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1)(link to form) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)			X		
	a) All inerts (link to http://www.epa.gov/oppr001/inerts/), including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
		X				
3	Certification with Respect to Citation of Data (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)			X		
	Data Matrix (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)			X		
5		yes	no			
	a) Selective Method (Fee category experts use)	X				
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (link to http://www.epa.gov/opplead1/labeling/lrm/) (Electronic labels on CD are encouraged and guidance is available)(link to http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels)			X		

7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)	X		
8	Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)			X
9	If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)			X
10	Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

Comments:

Stories passed 86-3 Review

Inerts approved for non-food use

JB
08/17

MRID 481 892

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web

site [[link to http://www.epa.gov/opprd001/inerts/lists.html](http://www.epa.gov/opprd001/inerts/lists.html)] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [[Link to http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm](http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm)].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [[link to http://www.epa.gov/opprd001/inerts/tips.pdf](http://www.epa.gov/opprd001/inerts/tips.pdf)] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

*File
2017*

August 30, 2010

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

PLEASE RETURN A COPY OF THIS LETTER WITH PAYMENT

Or Pay On-Line at www.Pay.Gov (See Below for Details)

OPP Decision Number: D-438361

EPA File Symbol or Registration Number: 2517-RUE

Product Name: SERGEANT'S FIPRONIL + CYPHENOTHIN + METHOPRENE SQUEEZE-
ON FOR DOGS

EPA Receipt Date: 11-Aug-2010

EPA Company Number: 2517

Company Name: SERGEANT'S PET CARE PRODUCTS, INC.

KELLY R. HOSKINS

SERGEANT'S PET CARE PRODUCTS, INC.

2625 SOUTH 158TH PLAZA

OMAHA, NE 68130-1703

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application for registration. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action previously identified as R310 has been reclassified as Action Code: R320

NEW PRODUCT;NON-FAST TRACK;NEW PHYSICAL FORM (EXCLUDES SELECTIVE CITATIONS);

The fee associated with this action is \$ 5,712 (50% of \$ 11,424). Payment in the amount of \$ 2,289 has been received. Please remit additional payment in the amount of \$ 3,423.

By USPS:

USEPA Washington Finance Center

Pesticide Registration Service Fee

PO Box 979074

St. Louis, MO 63197-9000

By Courier:
U.S. Bank
Government Lockbox 979074
1005 Convention Plaza
SL-MO-C2-GL
St. Louis, MO 63197
Telephone: (412) 236-2294

All payments must be in United States currency by check, bank draft, or money order drawn to the order of the Environmental Protection Agency. To ensure proper credit, please write the OPP DECISION NUMBER on your check, and enclose a copy of this letter with your payment.

Effective November 1, 2006, fees may be paid on-line via credit card or electronic fund transfer. To submit a payment on-line, visit www.pay.gov. From the pay.gov home page, select "search by form name." From the next page, select "P," then click on "Pesticide Registration Improvement Act. Fee Payment" and complete the form, making certain to use the decision number and registration number on the invoice you receive from the Pesticide Program in the space provided.

You may be eligible for a partial waiver of the registration service fee if, for example, you qualify as a small business or are applying for a minor use, or if your application is solely associated with an IR-4 tolerance petition. Please be advised that if you intend to request a waiver, you must do so in writing within 15 days of receipt of this invoice instead of remitting the amount indicated above. OPP will not consider waiver requests after the registration service fee has been paid. Information regarding eligibility and how to request and document a fee waiver is available on the OPP Fee for Service web site at www.epa.gov/pesticides/fees.

Please send Registration Service Fee Waiver requests to:

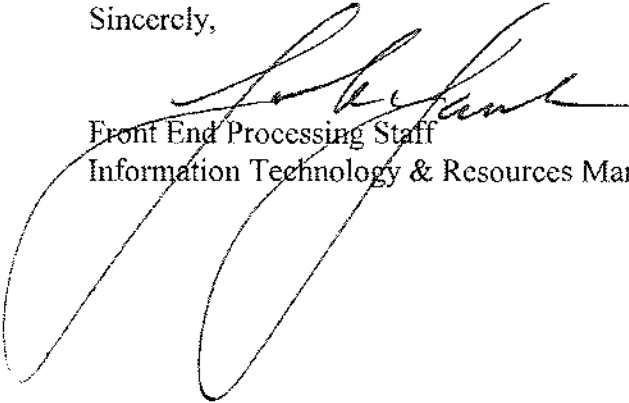
By USPS:
Document Processing Desk (WAIVER)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave NW
Washington, DC 20460

By Courier:
Document Processing Desk (WAIVER)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room S4900 Potomac Yard 1
2777 S. Crystal Dr.
Arlington, VA 22202

A PRIA decision time review period will not start until a fee waiver is granted and/or the Agency receives certification that the outstanding fee has been paid. If the Agency does not receive certification of payment for this action or a fee waiver request within the next 30 days, the Agency will presume that you no longer want to pursue this action. The Agency will then reject your application and issue an invoice for any applicable outstanding fees.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,



Front End Processing Staff
Information Technology & Resources Management Division



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

August 12, 2010

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-438361
EPA File Symbol or Registration Number: 2517-RUE
Product Name: SERGEANT'S FIPRONIL + CYPHENOTHIN + METHOPRENE SQUEEZE-
ON FOR DOGS
EPA Receipt Date: 11-Aug-2010
EPA Company Number: 2517
Company Name: SERGEANT'S PET CARE PRODUCTS, INC.

KELLY R. HOSKINS
SERGEANT'S PET CARE PRODUCTS, INC.
2625 SOUTH 158TH PLAZA
OMAHA, NE 68130-1703

SUBJECT: Receipt of Application and 50% Small Business Waiver Request

Dear Registrant:

The Office of Pesticide Programs has received your application, 50% small business waiver request, and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R310
NEW PRODUCT;NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT
CHEMISTRY;ACUTE TOXICITY;PUBLIC HEALTH PEST EFFICACY);

Your request for waiver has been forwarded for review. You will be notified in writing when a determination is made regarding your request. If your waiver request is approved, the decision review time period will start on the date of approval. If your waiver request is denied, you will receive an invoice for the outstanding balance.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

Teresa Brown
Front End Processing Staff

Information Technology & Resources Management Division



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

August 16, 2010

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SERGEANT'S PET CARE PRODUCTS, INC.
2625 SOUTH 158TH PLAZA
OMAHA, NE 68130-1703

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 11-AUG-10. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Fee for Service

{880182\$~

This package includes the following

- ☒ New Registration
- ☐ Amendment

☒ Studies? ☒ Fee Waiver?

☐ volpay % Reduction: 50

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. 10

Receipt No.

S- 880182

EPA File Symbol/Reg. No.

2517-RUE

Pin-Punch Date:

8/11/2010

☐ This item is NOT subject to FFS action.

Action Code:

Requested: R310

Granted: R310

Amount Due: \$ 4.578

Parent/Child Decisions:

☐ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: W. Onish Date: 8/12/10

Remarks:

Receipt for Section 3

S: 880182

Regulatory Type: Product Registration - Section 3

Fee For Service: ☒ Yes ☐ No

Application Type: New Registration

Billable: ☒ Yes ☐ No

Print Letter

Enter More Information

Tracking

Company: 2517 SERGEANT'S PET CARE PRODUCTS, INC.

V

Risk Manager: Registration Division, Risk Management Team 10

Product #: 2517-RUE

Product Name: SERGEANT'S FIPRONIL + CYPHENOTHRIN + M

Me Too

Section 3:

Me Too

Product Name:

Application Date: 11-Aug-2010

id

OPP Rec'd Date: 11-Aug-2010

id

Front End Date: 12-Aug-2010

id

Risk Manager Send Date:

id

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Receipt Content

Study

CSF

View/Edit

Fast Track:

New Ingredient:

Receipt Description:

NEW END-USE PRODUCT REGISTRATION APPLICATION

FEE FOR SERVICE

Online Payment

Step 3: Confirm Payment

1 | 2 | 3

Thank you.

Your transaction has been successfully completed.

Pay.gov Tracking Information

Application Name: PRIA Service Fees

Pay.gov Tracking ID: 2510IM08

Agency Tracking ID: 74122352649

Transaction Date and Time: 06/18/2010 14:38 EDT

Payment Summary

Account Holder Name: Sergeant's Pet Care Products, Inc

Payment Amount: \$2,289.00

Account Type: Business Checking

Routing Number: [REDACTED]

Account Number: *****5483

Payment Date: 06/21/2010

Decision Number:

Registration Number: 2517-new

Company Name: Sergeant's Pet Care Products, Inc

Company Number: 2517

Action Code: R310

Commercial/financial information may be entitled to confidential treatment

Receipt for Section 3

S: 880182

Regulatory Type: Product Registration - Section 3

Fee For Service: ☒ Yes ☐ No

Application Type: New Registration

Billable: ☒ Yes ☐ No

Company: 2517 SERGEANT'S PET CARE PRODUCTS, INC.

V

Risk Manager: Registration Division, Risk Management Team 10

Product #: 2517-RUE Product Name: SERGEANT'S FIPRONIL + CYPHENOTHRIIN + I

Me Too
Section3:

Me Too
Product Name:

Application Date: 11-Aug-2010

OPP Rec'd Date: 11-Aug-2010

Front End Date: 12-Aug-2010

Risk Manager Send Date:

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track:

New Ingredient:

Receipt Description:

NEW END-USE PRODUCT REGISTRATION APPLICATION

Print Letter

Enter More Information

Tracking

Receipt Content

Study

CSF

View/Edit



ADMINISTRATIVE NO(S): 2517 - PUE

PM: 10

CHEMICAL NO.: _____

The jacket for this action can be
requested through the JACKETS system.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

September 7, 2010

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-438361
EPA File Symbol or Registration Number: 2517-RUE
Product Name: SERGEANT'S FIPRONIL + CYPHENOTHHRIN + METHOPRIFNE SQUEEZE-
ON FOR DOGS
EPA Application Receipt Date: 11-Aug-2010
EPA Waiver Request Receipt Date: 11-Aug-2010
EPA Company Number: 2517
Company Name: SERGEANT'S PET CARE PRODUCTS, INC.

KELLY R. HOSKINS
SERGEANT'S PET CARE PRODUCTS, INC.
2625 SOUTH 158TH PLAZA
OMAHA, NE 68130-1703

SUBJECT: Approval of 50% Small Business Waiver Request

Dear Registrant:

The Office of Pesticide Programs has approved your request for 50% waiver of the pesticide registration fee associated with the action referenced above. The decision review period for this action will begin on the date of this letter.

The Action has been identified as Action Code: R320

NEW PRODUCT;NON-FAST TRACK;NEW PHYSICAL FORM (EXCLUDES SELECTIVE CITATIONS);

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman, at (703) 308-9362.

Sincerely,

A handwritten signature in black ink, appearing to read "Oscar Morales", followed by the word "for" in a cursive script.

Oscar Morales, Director
Information Technology & Resources Management Division
Office of Pesticide Programs

August 11, 2010

Richard Gebken, PM10
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Document Processing Desk
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject: Child Resistant Packaging Certification
Sergeant's Fipronil + Cyphenothrin + Methoprene Squeeze-On for Dogs
EPA File Symbol 2517-NEW *RUE*

Dear Mr. Gebken:

I certify that the packaging used for the following product meets the standards of 40 CFR 157.32, including the revised standards in 16 CFR 1700.15(b), when tested by the revised testing procedures in 16 CFR 1700.20, as published in 60 FR 37710 (July 21, 1995):

- Sergeant's Fipronil + Cyphenothrin + Methoprene Squeeze-On for Dogs (EPA File Symbol 2517-NEW)

Sergeant's Pet Care Products, Inc. (Sergeant's, 2625 South 158th Plaza, Omaha, NE 68130-1770, EPA Company Number 2517) is submitting this child resistant packaging certification to support for the new end-use product for Sergeant's Fipronil + Cyphenothrin + Methoprene Squeeze-On for Dogs (EPA File Symbol 2517-NEW). All product labels have language specifying the use of scissors to open the product container and label language stating the product is not to be applied by children.

If you have any questions, please contact me at 402-938-7079.

Sincerely,

Kelly R. Hoskins / ZAT

Kelly R. Hoskins
Manager of Technical Affairs

cc: Larry Nouvel

August 11, 2010

Rosalind Gross
 c/o Richard Gebken
 Registration Division
 Office of Pesticide Programs (7504P)
 U.S. Environmental Protection Agency
 Document Processing Desk
 Room S-4900, One Potomac Yard
 2777 South Crystal Drive
 Arlington, VA 22202

Subject: Child Resistant Packaging Support
 Sergeant's Fipronil + Cyphenothrin + Methoprene Squeeze-On for Dogs (EPA
 File Symbol: 2517-NEW) *RUE*

Dear Ms. Gross:

Sergeant's Pet Care Products, Inc. (EPA Company Number 2517) is submitting a request to rely on previously submitted Child Resistant Packaging (CRP) studies to support this new registration. The CRP data were submitted to EPA on April 12, 2010 in support of the pending registration applications under EPA File Symbols: 2517-RGT, 2517-RGA, 2517-RGL, and 2517-RGU (all of which contain Fipronil at 9.7-9.8%).

Sergeant's generated CRP data on a standard white applicator in sizes 0.5, 0.67, 1.34, 2.68, and 4.02 mL. The following is a summary table of the applicators that were tested and submitted to EPA in the CRP data:

Use	Applicator Base Color	Fill Weight (mL)	Color
Dog Up to 22 lbs	White	0.67	Orange
Dog 23-44 lbs	White	1.34	Green
Dog 45-88 lbs	White	2.68	Red
Dog 89-132 lbs	White	4.02	Blue
Cats All Weights	White	0.50	Purple

CRP data is required for this new product because of the inclusion of the active ingredient fipronil (9.8%) in the pet squeeze-on product. The CRP testing was conducted on a standard package size and color configuration for a product containing fipronil (9.8%). The Sergeant's Fipronil + Cyphenothrin + Methoprene Squeeze-On for Dogs product being submitted today also contains fipronil at 9.8%. Additionally, Sergeant's already has dog squeeze-on products approved by EPA containing 20-30% cyphenothrin (EPA Registration Numbers 2517-127 through 2517-132) that are not subject to CRP. This new product contains 5% cyphenothrin and

8.8 % methoprene. Additionally, there are EPA registered products containing s-methoprene, none of which are subject to CRP.

Furthermore, Sergeant's does not anticipate any additional toxicity through the combination of fipronil, cyphenothrin and methoprene. When Sergeant's Fipronil + Cyphenothrin + Methoprene Squeeze-On for Dogs is marketed, it will have the same applicator color (white) and fill weight colors per mL fill weight as was used in the submitted and referenced CRP testing. Based on available information, the density range of the pending products on which the CRP data were generated is the same as the new product (1.0-1.5 gr/cc). Therefore, Sergeant's is relying on MRID's: 48059803, 48059804, 48059805, and 48059806 to fulfill the CRP data requirements for Sergeant's Fipronil + Cyphenothrin + Methoprene Squeeze-On for Dogs.

If you have any questions, please contact me at 402-938-7079.

Sincerely,

Kelly R. Hoskins /ZAT

Kelly R. Hoskins
Manager of Technical Affairs

cc: Larry Nouvel

August 11, 2010

Richard Gebken, PM10
Office of Pesticide Programs (7504P) (REGFEE)
U.S. Environmental Protection Agency
Document Processing Desk
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject: Sergeant's Fipronil + Cyphenothrin + Methoprene Squeeze-On for Dogs
EPA File Symbol 2517-NEW ~~REG~~

Dear Mr. Gebken:

Sergeant's Pet Care Products, Inc. (Sergeant's, 2625 South 158th Plaza, Omaha, NE 68130-1770, EPA Company Number 2517) is submitting an EPA registration application for the new product Sergeant's Fipronil + Cyphenothrin + Methoprene Squeeze-On for Dogs [containing the EPA registered active ingredients Fipronil (9.8%), Cyphenothrin (5.0%), and s-Methoprene (8.8%)]. Please find enclosed the following documentation in support of this registration:

- (1) Transmittal Document;
- (2) Application for Registration (EPA Form 8570-1);
- (3) Confidential Statement of Formula (EPA Form 8570-4) (two copies);
- (4) Certification with Respect to Citation of Data (EPA Form 8570-34);
- (5) Formulator's Exemption Statement (EPA Form 8570-27);
- (6) Data Matrix (EPA Form 8570-35) – EPA and Public Versions;
- (7) Product Label (five copies);
- (8) Letter of Authorization;
- (9) Child Resistant Package (CRP) Certification Statement;
- (10) Bridging Argument to Cite CRP Data;
- (11) Submission of EPA Pesticide Registration Improvement Act Information;
- (12) Voluntary Small Business Certification Form;
- (13) PRIA Fee Waiver Certification Statement;
- (14) PRIA Fee Waiver Support Letter;
- (15) Recent EPA Approval of 50% Small Business Waiver Request (D-425455);
- (16) PRIA Category R310, Payment Confirmation Receipt; and
- (17) Three Copies of Supporting Studies.

The registration of Sergeant's Fipronil + Cyphenothrin + Methoprene Squeeze-On for Dogs is a selective citation registration for a new end-use product. Sergeant's is submitting new product chemistry studies in support of this end-use product registration, and one new efficacy study. Additionally, Sergeant's is citing acute toxicity studies, companion animal safety data and efficacy studies submitted to EPA on June 18, 2010 with the registration application for



Sergeant's Pet Care Products, Inc.

2625 South 158th Plaza • Omaha, NE 68130-1770 • Telephone 402.938.7000 • Fax 402.938.7091 • www.sergeants.com

Sergeant's Fipronil + Cyphenothrin Squeeze-On for Dogs. The acute toxicity studies were conducted on a "soup" that contains multiple active ingredients that can be bridged across multiple formulated end-use products.

This registration application is considered a PRIA Category R310 (new end-use product) with a PRIA review time of 6 months. Sergeant's submitted a PRIA Small Business Waiver Request under separate cover on April 14, 2010, and it was approved by EPA on May 4, 2010. A copy of this approval letter is enclosed.

We look forward to working with the Agency to register Sergeant's Fipronil + Cyphenothrin + Methoprene Squeeze-On for Dogs. If you have any questions or need additional information regarding this registration application, please contact me at 402-938-7079.

Sincerely,

Kelly R. Hoskins /ZAT

Kelly R. Hoskins
Manager of Technical Affairs

Enclosures

EPA
 United States
Environmental Protection Agency
 Washington, DC 20460

☒ **Registration**
☐ **Amendment**
☐ **Other**

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 2517-NEW <i>RUE</i>	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Sergeant's Pet Care Products, Inc./ Sergeant's Fipronil + Cyphenothrin + Methoprene Squeeze-On For Dogs	5. PM# 10	
5. Name and Address of Applicant (Include ZIP Code) Sergeant's Pet Care Products, Inc. 2625 South 158 th Plaza Omaha, NE 68130-1770 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated XX-XX-XX
<input type="checkbox"/> Resubmission in response to Agency letter dated XX-XX-XX	<input type="checkbox"/> "Me Too" Application
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)
 Submission of a new end-use product registration application.

Section III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) Plastic Bag
*Certification must be submitted		If "Yes" Unit Packaging wgt. No. per Container 0.023 fl oz (0.67 ml) 3 vials 0.045 fl oz (1.34 ml) 0.091 fl oz (2.68 ml) 0.136 fl oz (4.02 ml)	If "Yes" Package wgt. No. per Container _____
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 0.067 ml, 1.34 ml, 2.68 ml, 4.02 ml	5. Location of Label Directions <input type="checkbox"/> On Car. <input checked="" type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Other _____ <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Kelly R. Hoskins	Title Manager of Technical Affairs	Telephone No. (Include Area Code) 402-938-7079
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature BY: <i>Kelley R. Hoskins / ZAT</i>	3. Title Manager of Technical Affairs	
4. Typed Name: Kelly R. Hoskins	5. Date: 08/11/2010	

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

Sergeant's Pet Care Products, Inc.
2625 South 158th Plaza
Omaha, NE 68130-1770

CONTACT PERSON (Return to)

Kelly R. Hoskins
Sergeant's Pet Care Products, Inc.
2625 South 158th Plaza
Omaha, NE 68130-1770

REGULATORY ACTION SUPPORTED BY THIS PACKAGE:

This submission is prepared to support an EPA registration application for the new end-use product Sergeant's Fipronil + Cyphenothrin + Methoprene Squeeze-On for Dogs.

SUBMITTAL DATE:

August 11, 2010

Volume	Study Title	MRID No.
1	Administrative Materials	
2	Group A Product Chemistry for Sergeant's Fipronil + Cyphenothrin + Methoprene Squeeze-On for Dogs	
3	Group B Product Chemistry for Sergeant's Fipronil + Cyphenothrin + Methoprene Squeeze-On for Dogs	
4	Dose Titration with S-Methoprene Squeeze-Ons on Dogs Measuring Flea Egg Sterilization.	



United States
Environmental Protection Agency
 Washington, DC 20460
Formulator's Exemption Statement
 (40 CFR 152.85)

Applicant's Name and Address Sergeant's Pet Care Products, Inc. 2625 South 158th Plaza Omaha, NE 68130-1770	EPA File Symbol/Registration Number 2517-NEW RUC
	Product Name Sergeant's Fipronil + Cyphenothrin + Methoprene Squeeze-On for
	Date of Confidential Statement of Formula (EPA Form 8570-4) 08/11/2010

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Fipronil
 S-methoprene
 Cyphenothrin

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
Fipronil		
S-methoprene		
S-methoprene		
Cyphenothrin		
Signature 	Name and Title Kelly R. Hoskins, Manager of	Date 08/11/2010

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 - EPA
 Copy 2 - Applicant copy

Product ingredient source information may be entitled to confidential treatment



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Sergeant's Pet Care Products, Inc., 2625 South 158th Plaza, Omaha, NE 68130-1770	EPA Registration Number/File Symbol 2517-NEW
Active Ingredient(s) and/or representative test compound(s) Fipronil, Cyphenothrin, and S-methoprene	Date 08/11/2010
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Domestic indoor non-food	Product Name Sergeant's Fipronil + Cyphenothrin + Methoprene

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature <i>Kelley R. Hoskins / ZAT</i>	Date 08/11/2010	Typed or Printed Name and Title Kelly R. Hoskins, Manager of Technical Affairs
---	--------------------	---

R 310

Must submit Group A and B product chemistry data for each proposed product.

End Use (EP) or Manufacturing Use (MP) product or Technical Grade of the Active Ingredient (TGA)

Guideline No.	Group A: Product Chemistry Data Study Title	EP Data Submitted		MP Data Submitted		TGA	
		Yes	No	Yes	No	Yes	No
830.1550	Product Identity & Composition	✓					
830.1600	Description of materials used to produce the product	✓					
830.1650	Description of formulation process	✓					
830.1670	Discussion on the formation of impurities	✓					
830.1700	Preliminary analysis		✓				
830.1750	Certified limits (158.345)	✓					
830.1800	Enforcement analytical method (its being used) ✓						

Guideline No.	Group B: Product Chemistry Data Study Title	EP Data Submitted		MP Data Submitted		TGA	
		Yes	No	Yes	No	Yes	No
830.6302	Color	✓					
830.6303	Physical State	✓					
830.6304	Odor	✓					
830.6313	Stability to normal and elevated temperatures metal and metal ions						
830.6314	Oxidation/Reduction (Chemical incompatibility)	✓					
830.6315	Flammability	✓					
830.6316	Explosibility	✓					
830.6317	Storage stability	✓					
830.6319	Miscibility	✓					
830.6320	Corrosion Characteristics	✓					
830.6321	Dielectric Breakdown Voltage	✓					
830.7000	pH	✓					
830.7050	UV/ Visible Absorption						
830.7100	Viscosity	✓					
830.7200	Melting Point						
830.7220	Boiling Point						
830.7300	Density	✓					
830.7370	Dissociation Constant						
830.7550	Partition Coefficient						
830.7840	Water Solubility						
830.7950	Vapor Pressure						

Grayed out = data not required

R 310

New products must either: 1) supply the product specific acute toxicity 6 pack data (listed below), or 2) provide a bridging rationale document. The bridging document directs OPP to use a currently registered set of 6 acute toxicity data and label; instead of submitting product specific data.

Guideline No.	Acute toxicity (6 pack) Study Title	Data submitted		Cited	
		Yes	No	Yes	No
870.1100	Acute Oral (LD50)			✓	
870.1200	Acute Dermal (LD50)			✓	
870.1300	Acute Inhalation (LC50)			✓	
870.2400	Acute Eye Irritation			✓	
870.2500	Acute Dermal Irritation			✓	
870.2600	Dermal Sensitization			✓	

Efficacy – which guideline is used depends on the proposed label use

Guideline No.	Study Title	Data submitted		Cited		Comments
		Yes	No	Yes	No	
810.3100	Soil Treatments for Imported Fire Ants					
810.3200	Livestock, Poultry, Fur and Wool-Bearing Animal Treatments					
810.3300	Treatments to Control Pests of Humans and Pets			✓		
810.3400	Mosquito, Black Fly, and Biting Midge (Sand Fly) Treatments					
810.3500	Premises Treatments					
810.3600	Structural Treatments					
810.3800	Methods for Efficacy Testing of Termite Baits					

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DATA MATRIX

Date: August 11, 2010		EPA Reg No./File Symbol 2517-NEW RUC		Page 1 of 4	
Applicant's/Registrant's Name & Address Sergeant's Pet Care Products, Inc. 2625 South 158th Plaza, Omaha, NE 68130-1770		Product: Sergeant's Fipronil + Cyphenothrin + Methoprene Squeeze-On for Dogs			
Ingredients: Fipronil, Cyphenothrin and (s)-Methoprene					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550, 830.1600, 830.1620, 830.1650, 830.1670, 830.1750	Group A Product Chemistry for Sergeant's Fipronil + Cyphenothrin + Methoprene Squeeze-On for Dogs	New submission	Sergeant's Pet Care Products, Inc.	OWN	
830.1800	Enforcement analytical method	48122601	Sergeant's Pet Care Products, Inc.	OWN	
830.6302, 830.6303, 830.6304, 830.6313, 830.6314, 830.6315, 830.6316, 830.6317, 830.6319, 830.6320, 830.6321, 830.7000, 830.7100, 830.7300, 830.7520	Group B Product Chemistry for Sergeant's Fipronil + Cyphenothrin + Methoprene Squeeze-On for Dogs	New submission	Sergeant's Pet Care Products, Inc.	OWN	
830.6317, 830.6320	Storage stability and corrosion characteristics	To Be Submitted Upon Completion	Sergeant's Pet Care Products, Inc.	OWN	
870.1100	Acute Oral Toxicity Up and Down Procedure with Dog Products	48129603	Sergeant's Pet Care Products, Inc.	OWN	
870.1200	Acute Dermal Toxicity (Limit Test) with Dog Products	48129604	Sergeant's Pet Care Products, Inc.	OWN	
870.1300	Waiver Request of Requirement for Further Testing for Acute Inhalation Toxicity	48129605	Sergeant's Pet Care Products, Inc.	OWN	
870.2400	Acute Eye Irritation/Corrosion with Dog Products	48129606	Sergeant's Pet Care Products, Inc.	OWN	
870.2500	Acute Dermal Irritation/Corrosion with Dog Products	48129607	Sergeant's Pet Care Products, Inc.	OWN	
870.2600	Test for Sensitization (Guinea Pig Maximisation Test) with Dog Products	48129608	Sergeant's Pet Care Products, Inc.	OWN	
870.7200	Companion Animal Safety for Sergeant's Fipronil + Cyphenothrin Squeeze-On for Dogs	48129614	Sergeant's Pet Care Products, Inc.	OWN	
870.7200	Companion Animal Safety Study in Dogs - Cyphenothrin-IGR Spot-On for Dogs	46166108	Sergeant's Pet Care Products, Inc.	OWN	
870.7200	Companion Animal Safety Evaluation on Drop of Spot-On Products Containing Multiple Toxicants and Insect Growth Regulators	47849609	Sergeant's Pet Care Products, Inc.	OWN	
870.7200	Assessment of Tolerance of a 0.25% RM 1601 Spray Formulation in Dogs at 3, 9, and 15 ml/kg When Applied 6 times to the Haircoat at 28 Day Intervals	43121110	Meril Limited	OLD	
Signature: Kelly R Hoskins /ZAT		Name and Title Kelly R. Hoskins, Manager of Technical Affairs			Date 08/11/2010

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DATA MATRIX

Date: August 11, 2010		EPA Reg No./File Symbol 2517-NEW		Page 2 of 4	
Applicant's/Registrant's Name & Address Sergeant's Pet Care Products, Inc. 2625 South 158th Plaza, Omaha, NE 68130-1770		Product: Sergeant's Fipronil + Cyphenothrin + Methoprene Squeeze-On for Dogs			
Ingredients: Fipronil, Cyphenothrin and (s)-Methoprene					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.7200	Domestic Animal Safety: Assessment of the Tolerance of a 0.25% RM 1601 Spray in Nursing Puppies Administered Twice at a 28 Day Interval at a Dose Rate of 6 ml/kg:	43121111	Merial Limited	OLD	
870.7200	Domestic Animal Safety Study of RM1601C Topical Spray (Frontline Spray Treatment) in Juvenile Dogs:	43444905	Merial Limited	OLD	
870.7200	Discussion in Support of Bridging Domestic Animal Safety Data on Frontline Spray Treatment to Frontline Spot Treatment Data Package.	43577711	Merial Limited	OLD	
870.7200	Domestic Animal Safety Study by Topical Administration to Dogs: Fipronil Spot Treatment (RM 1601E)	43863802	Merial Limited	OLD	
810.3300	Dose Titration with (S)-Methoprene Squeeze-Ons on Dogs Measuring Flea Egg Sterilization.	New submission 48189203	Sergeant's Pet Care Products, Inc.	OWN	
810.3300	Overview and Summary of Fipronil/Cyphenothrin Dog Efficacy for Sergeant's Fipronil + Cyphenothrin Squeeze-On for Dogs	48129609	Sergeant's Pet Care Products, Inc.	OWN	
810.3300	Immediate Efficacy of a Combined Application of Frontline Plus with Cyphenothrin as a Squeeze-on against Fleas (<i>Ctenocephalides felis</i>) and Ticks (<i>Rhipicephalus sanguineus</i>) on Dogs MS 164 D	48129610	Sergeant's Pet Care Products, Inc.	OWN	
810.3300	Immediate Efficacy Following Application of Frontline Plus with Cyphenothrin Squeeze-on against Fleas (<i>Ctenocephalides felis</i>) and Ticks (<i>Rhipicephalus sanguineus</i>) on Dogs MS 183 D	48129611	Sergeant's Pet Care Products, Inc.	OWN	
810.3300	Immediate Efficacy Following Application of Frontline with Cyphenothrin Squeeze-on against Fleas (<i>Ctenocephalides felis</i>) and Ticks (<i>Rhipicephalus sanguineus</i>) on Dogs MS 175 D	48129612	Sergeant's Pet Care Products, Inc.	OWN	
810.3300	Comparative efficacy evaluation of Sergeant's Squeeze-on and Frontline Plus for the treatment of adult cat flea (<i>Ctenocephalides felis</i>) and tick (<i>Haemaphysalis elliptica</i> , <i>Rhipicephalus sanguineus</i> and <i>Dermacentor variabilis</i>) infestations on dogs	48129613	Sergeant's Pet Care Products, Inc.	OWN	
810.3300	A Dose Titration Study to Determine the Optimal Spray Concentration of RM 1601 for Long Term Control of the Cat Flea <i>Ctenocephalides felis</i> and the Brown Dog Tick <i>Rhipicephalus sanguineus</i> in the Dog	43121114	Merial Limited	OLD	
Signature: Kelly R. Hoskins / ZAT			Name and Title Kelly R. Hoskins, Manager of Technical Affairs		Date 08/11/2010

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Applicant's/Registrant's Name & Address Sergeant's Pet Care Products, Inc. 2625 South 158th Plaza, Omaha, NE 68130-1770		Product: Sergeant's Fipronil + Cyphenothrin + Methoprene Squeeze-On for Dogs			
Ingredients: Fipronil, Cyphenothrin and (s)-Methoprene					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
810.3300	Product Performance: A Dose Confirmation Study to Verify the Optimal Spray Concentration of RM 1601 for Long Residual Control of the Cat Flea (<i>Ctenocephalides felis</i>) and the Brown Dog Tick (<i>Rhipicephalus sanguineus</i>) in the Dog	43121115	Merial Limited	OLD	
810.3300	A Comparative Evaluation of Two Treatment Regimes Using RM 1601 Spray for Control of the Cat Flea <i>Ctenocephalides felis</i> on the Dog:	43121116	Merial Limited	OLD	
810.3300	Laboratory Evaluation of RM 1601 Spray for Control Dermacentor variabilis and Rhipicephalus sanguineus on the Dog	43121117	Merial Limited	OLD	
810.3300	An Investigation Study to Evaluate the Effect of Bathing of Laboratory Dogs on the Efficacy of RM1601 Spray	43121118	Merial Limited	OLD	
810.3300	Efficacy of RM1601C at 3 ml/kg and 6 ml/kg Against Ixodes scapularis/dammini Nymphs, Dermacentor variabilis Nymphs, Amblyomma americanum Nymphs, Rhipicephalus sanguineus Nymphs, and Ctenocephalides felides Adults Using Treated Dog Hair as the Testing Substrate	43121122	Merial Limited	OLD	
810.3300	Positive Referenced and Untreated Controlled, Confirmatory Laboratory Trial of RM1601E SPOT-ON Formulation Applied to Dogs as 3 Weight Class Defined Volumes for the Control of the Cat Flea <i>Ctenocephalides felis</i> , the Brown Dog Tick <i>Rhipicephalus sanguineus</i> , and the American Dog Tick <i>Dermacentor variabilis</i>	43577712	Merial Limited	OLD	
810.3300	Study Summaries: Frontline Plus For Dogs.	45612701	Merial Limited	PAY	
810.3300	An Efficacy Study of Frontline Spray, Frontline Top Spot, and ML-2,095,988 509T, for the Treatment and Control of Trichodectes canis in the Dog	45620501	Merial Limited	PAY	
810.3300	PR & D 0024101: Frontline Spray/ Frontline Spot-On/ML-2, 095, 988 509T/Dogs /Solution/Topical	45620504	Merial Limited	PAY	
810.3300	PR & D 0052301: Frontline Spray/Frontline Spot-On/ML-2, 095, 988 509T/Dogs/ Solution/ Topical	45620505	Merial Limited	PAY	
810.3300	Frontline Spray & Top Spot/ Dogs/Solution/Topical Clinical/Dose Confirmation/ Ectoparasites, Mites, Sarcoptes Scabiei var canis	45620506	Merial Limited	PAY	
Signature: Kelly R. Hoskins /ZAT			Name and Title Kelly R. Hoskins, Manager of Technical Affairs		Date 08/11/2010

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Applicant's/Registrant's Name & Address Sergeant's Pet Care Products, Inc. 2625 South 158th Plaza, Omaha, NE 68130-1770		Product: Sergeant's Fipronil + Cyphenothrin + Methoprene Squeeze-On for Dogs			
Ingredients: Fipronil, Cyphenothrin and (s)-Methoprene					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
810.3300	Study to Confirm the Efficacy of Fipronil Against Lice in Dogs Under Field Conditions	45628201	Merial Limited	PAY	
810.3300	A Study to Evaluate the Efficacy of Frontline Plus for Control of Mosquitoes, <i>Aedes aegypti</i> , on Dogs	45866902	Merial Limited	PAY	
810.3300	Effect of Shampoo Application after Treatment with a Cyphenothrin Squeeze-On on Efficacy Against Cat Fleas (<i>Ctenocephalides felis</i>), Adult Brown Dog Ticks (<i>Rhipicephalus sanguineus</i>) on Dogs	46298501	Sergeant's Pet Care Products, Inc.	OWN	
40 CFR Part 157.32	Evaluation of the Dog Squeeze On 0.67 ml White Applicator with Orange Label Indicator (3x), scissors to open - F=1 as a Poison Prevention Package for Sergeant's Pet Care Products, Inc.	48059803	Sergeant's Pet Care Products, Inc.	OWN	
40 CFR Part 157.32	Evaluation of the Dog Squeeze On 1.34 ml White Applicator with Green Label Indicator (3x), scissors to open - F=1 as a Poison Prevention Package for Sergeant's Pet Care Products, Inc.	48059804	Sergeant's Pet Care Products, Inc.	OWN	
40 CFR Part 157.32	Evaluation of the Dog Squeeze On 2.68 ml White Applicator with Red Label Indicator (3x), scissors to open - F=1 as a Poison Prevention Package for Sergeant's Pet Care Products, Inc.	48059805	Sergeant's Pet Care Products, Inc.	OWN	
40 CFR Part 157.32	Evaluation of the Dog Squeeze On 4.02 ml White Applicator with Blue Label Indicator (3x), scissors to open - F=1 as a Poison Prevention Package for Sergeant's Pet Care Products, Inc.	48059806	Sergeant's Pet Care Products, Inc.	OWN	
Signature: <i>Kelly R. Hoskins / ZAT</i>		Name and Title Kelly R. Hoskins, Manager of Technical Affairs		Date 08/11/2010	

Sergeant's® Master Label

11 August 2010

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Page 1 of 8

[CARTON LABEL - DRAFT MASTER LABEL COPY]

Sergeant's Fipronil + Cyphenothrin + Methoprene Squeeze-On for Dogs

[ABNs]

[(Sergeant's®) (Sentry®) VetSpot™ (Spot On) for dogs]

[(Sergeant's®) (Sentry®) VetSpot™ (Spot On) for dogs]

[(Sergeant's®) (Sentry®) FRONTIER GOLD (Spot On) for dogs]

[(Sergeant's®) (Sentry®) Ectoadvance™ (Spot On) for dogs]

Superseded

FRONT PANEL

DOG SQUEEZE ON

FIPRONIL+CYPHENOTHRIN+METHOPRENE

[Apply to puppies over 12 weeks old]

[Apply to puppies 12 weeks or older]

- [• Flea & Tick Control for Dogs & Puppies 12 weeks old and older]
- [• For Dogs and Puppies 12 weeks of age or older]
- [• For Dogs [up to 22 lbs], [23-44 lbs], [45-88 lbs], [89-132 lbs]]
- [• Kills fleas (in as little as 1 hour), flea eggs, ticks (in as little as 1 hour), chewing lice & mosquitoes]
- [• Kills (and Repels) Fleas, Ticks and Mosquitoes]
- [• Controls flea reinfestation for up to [16 weeks]]
- [• Fast Acting]
- [• Kills ticks (in as little as 1 hour)]
- [• Kills ticks including those that may transmit Lyme disease]
- [• Dogs can be bathed 24 hours after treatment]
- [• Waterproof]
- [• Long Lasting]
- [• Research demonstrates that [brand name] kills adult fleas (in as little as 1 hour), flea eggs, flea larvae and pupae for up to four months.]
- [• [brand name] prevents development of all flea stages for up to four months.]
- [• Kills fleas (in as little as 1 hour), ticks (in as little as 1 hour), mosquitoes, (chewing) lice, flea eggs, larvae and pupae]
- [• Prevents all flea stages (adult fleas (in as little as 1 hour), flea eggs, flea pupae and flea larvae)]
- [• If dog is a high risk for flea re-infestation a once month application may be needed]
- [• Once a month treatment is recommended]
- [• A once monthly application is recommended for chewing lice.]
- [• Rapidly eliminates infestations with chewing lice]
- [• Monthly flea, tick, mosquito, lice, and flea egg protection]
- [• Monthly flea, tick, mosquito and lice protection]
- [• Kills flea eggs [larvae] [pupae] for up to 4 months]
- [• Aids in Control of Sarcoptic Mange]

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- [• Kills fleas (in as little as 1 hour), ticks (in as little as 1 hour), mosquitoes, flea eggs, and lice]
- [• [Seven] [7] Way Protection [Kills fleas (in as little as 1 hour), ticks (in as little as 1 hour), mosquitoes, lice, flea eggs, flea larvae and flea pupae]]
- [• 6 [Six] Way Protection! Kills fleas (in as little as 1 hour), ticks (in as little as 1 hour), mosquitoes, lice, flea eggs & flea larvae]
- [• [4 Week] [Flea and Tick & Treatment]
- [• [Four (4) Week] [Flea, Tick, Mosquito and Lice Control]
- [• With (S)-methoprene Insect Growth Regulator which Breaks the Flea Life Cycle]
- [• With (S)-methoprene to Break Flea Life Cycle]
- [• With Insect Growth Regulator to Break Flea Life Cycle]
- [• Triple Action [!]: Fipronil and Cyphenothrin with (S)-methoprene IGR Effectively Breaks the Flea Life Cycle]
- [• Triple Action [!]: Effectively Breaks the Flea Life Cycle[!]]
- [• Three Applications {for cartons with 3 applicators}] and/or [3 Month Supply] or [12 Week Supply]
- [• Best if used year round!]
- [• Kills & Repels Fleas (in as little as 1 hour) Up to [4 weeks]!]
- [• (ICON Showing 4 Week Protection)]
- [• 4 Week Dose!]
- [• 1 Month Dose!]
- [• Easy to Use Application]
- [• Specially Formulated for Dogs and Puppies]
- [• [Free] Calendar Stickers Inside!]
- [• [Free] Brochure Inside!]
- [• [Free] Brochure and Calendar Stickers Inside]
- [• Patented Technology]
- [• Kills Flea Eggs & Flea Larvae for [(4 months)]!]
- [• Prevents Flea Eggs From Developing Into Biting Adults]
- [• Kills Ticks (in as little as 1 hour) for Up to [4 weeks]!]
- [• Kills [all stages of] Deer Ticks (vector of Lyme Disease) for up to 4 weeks]
- [• Kills Ticks (in as little as 1 hour)]
- [• Kills Ticks including Deer Ticks for up to 4 weeks]
- [• Kills Brown Dog Ticks (in as little as 1 hour)]
- [• Kills [Brown], [American,] [and Lone Star] Dog Ticks for up to 4 weeks]
- [• Kills *Rhipicephalus sanguineus* for up to 4 weeks]
- [• When used monthly [brand name] completely breaks the flea life cycle and controls tick and chewing lice infestations.]
- [• Kills American Dog Ticks [(*Dermacentor variabilis*)] for up to 4 weeks!]
- [• Apply once every [4 weeks]!]
- [• 4 weeks Flea and Tick Treatment!]
- [• Once A Month Flea and Tick Treatment]
- [• Kills & Repels Fleas (in as little as 1 hour) and Ticks (in as little as 1 hour) for up to 4 weeks!]
- [• Kills all stages of the flea life cycle]
- [• Kills Fleas (in as little as 1 hour), Ticks (in as little as 1 hour), Flea Eggs & Flea Larvae for up to 16 Weeks]

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- [• [Kills mosquitoes]]
- [• Dogs can be bathed 24 hours after squeeze-on is applied]
- [• Prevents and controls reinfestations]
- [• [Free with purchase] [Free inside] Monthly Application Reminder [Magnet] [clip] [card]]

[For Dogs & Puppies (12 weeks or older and) up to 22 lbs.]

[For Dogs 23-44 lbs.]

[For Dogs 45-88 lbs.]

[For Dogs 89-132 lbs.]

[] - Denotes Optional Statements and/or Images that May be Used on Front, Back or Side Label Panels

[Ingredient Statement may be on front or back label]

ACTIVE INGREDIENTS:

Fipronil.....	9.8%
Cyphenothrin.....	5.0%
(S)-methoprene	8.8%

OTHER INGREDIENTS:..... 76.4%

TOTAL: 100.0%

KEEP OUT OF REACH OF CHILDREN

WARNING

See [Back][or][Side] [Label Panel[s] [or] [insert] for Additional Precautionary Statements

NET CONTENTS:

Contains (3) [0.023 fl oz] [0.67 ml] applicators

Contains (3) [0.045 fl oz] [1.34 ml] applicators

Contains (3) [0.091 fl oz] [2.68 ml] applicators

Contains (3) [0.136 fl oz] [4.02 ml] applicators

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BACK PANEL

DOG SQUEEZE ON

FIPRONIL+CYPHENOTHHRIN+METHOPRENE

[BACK/SIDE CARTON LABEL - MASTER LABEL]

[brand name] contains Fipronil, cyphenothrin, and the insect growth regulator (IGR) (S)-methoprene to effectively kill [and repel] Fleas [(in as little as 1 hour)], Ticks [(in as little as 1 hour)], and kills mosquitoes and (chewing) lice. The active ingredients in [brand name] work by collecting in the hair follicles and skin oils. This product features a sustained-release formula that discharges from the animal's hair follicles using the natural skin oils, resulting in fast acting [and long lasting] control of Fleas and Ticks [(in as little as 1 hour)], [and kills mosquitoes] and chewing lice [for 30 days].

[diagram with visual of fipronil collecting and being released from hair follicle]

READ ENTIRE LABEL BEFORE EACH USE.

USE ONLY ON DOGS AND PUPPIES OVER 12 WEEKS OF AGE.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS. WARNING. Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse. Harmful if swallowed. Harmful if absorbed through skin. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

FIRST AID

If In Eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for further treatment advice.
If On Skin Or Clothing	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
If Swallowed	<ul style="list-style-type: none">• Immediately call a poison control center or doctor.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Have person sip a glass of water if able to do so.• Do not give anything by mouth to an unconscious person.

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For more information on this pesticide product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-781-4738.

NOTE TO PHYSICIAN OR VETERINARIAN

Treat patient symptomatically

Sergeant's® Master Label

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Information in [] is optional.

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BACK PANEL

**DOG SQUEEZE ON
FIPRONIL+CYPHENOTHHRIN+METHOPRENE**

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. **READ ENTIRE LABEL [AND ENCLOSED DIRECTIONS] BEFORE EACH USE.**

DO NOT USE ON CATS. May be toxic and potentially fatal if applied to or ingested by cats. **FOR EXTERNAL USE ON DOGS ONLY.** Do not use on puppies under 12 weeks of age. Weigh your dog to be sure you are applying the right dose formulated for the weight of your pet. Do not treat your pet with more than one pesticide product at a time. Over dosing your animal can result in serious illness and even death. **Best if used year round.** Certain medications can interact with pesticides. Consult a veterinarian before using this product on debilitated, aged, medicated, pregnant, or nursing dogs. Consult a veterinarian before using on dogs with known organ dysfunction. **DO NOT USE ON CATS** or animals other than dogs. Separate the treated dog from all other dogs and cats for 24 hours after treatment has been applied. Cats and dogs that actively groom or engage in close physical contact with treated dog may be at risk of serious harmful effects. The most common signs of ingestion are excessive salivation and foaming at the mouth. If these symptoms occur immediately feed your dog and continue to monitor your pet for the next 24 hours. If symptoms persist call 1-800-781-4738 to talk to a veterinarian. Cats exhibiting these same symptoms from ingestion should be taken to the veterinarian immediately. If your dog is exhibiting signs of and/or are being treated for skin dermatitis, talk to your vet before applying any topical flea and tick control product.

Sensitivities may occur after using ANY pesticide product on pets. If signs of sensitivity occur bathe your dog with a mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately by calling 1-800-781-4738.

[[Outer Packaging or Insert Copy]]

How to open: Remove product tubes [vial] from the package. Separate one tube from the others. Holding the tube [vial] with notched end pointing up and away from the face and body, cut off the narrow end at the notches with scissors.

How to apply: Invert tube over dog and use open end to part dog's hair. Squeeze tube firmly to apply all of the solution to the dog's skin, as directed below. Repeat application may be made if necessary, but do not apply more often than once every 4 weeks.

FREQUENCY OF APPLICATION

Use [brand name] monthly for complete control of flea, tick [and] chewing lice [and to kill mosquitoes] [infestations]. [Studies show that] [brand name] kills fleas (in as little as 1 hour) for up to three months. If your pet is at high risk for flea reinfestation [, or in a highly infested environment], apply monthly. Apply monthly to control ticks, mosquitoes and chewing lice. [Brand name] kills mosquitoes within 24 hours for the first 7 days after treatment, then within 48 hours for up to 28 days. [Brand name] remains effective, even after bathing, water immersion, or exposure to sunlight. Allow treated area to dry thoroughly. Do not reapply for 30 days.

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BACK PANEL

DOG SQUEEZE ON FIPRONIL+CYPHENOTHHRIN+METHOPRENE

For Dogs Weighing up to 22 lbs.

{For cartons containing .67 ml (0.023 fl. oz.) applicator tubes}

Apply one tube (.67ml)(0.023 fl. oz.) [as a spot to the dog's back between the shoulder blades]
[from the back of the neck to a point midway between the neck and tail].

For Dogs Weighing Between 23-44 lbs.

{For cartons containing 1.34 ml (0.045 fl. oz.) applicator tube}

[Apply two tubes (.67 ml)(0.023 fl. oz.) as a spot on the dog's back between the shoulder blades]
[or] [Apply one tube (1.34 ml)(0.045 fl. oz.) as a spot to the dog's back between the shoulder
blades.] [from the back of the neck to a point midway between the neck and tail].

For Dogs Weighing Between 45-88lbs.

For cartons containing 2.68 ml (0.091 fl. oz.) applicator tube}

Apply one tube (2.68 ml)(0.091 fl. oz.) [as a spot on the dog's back between the shoulder blades]
[from the back of the neck to a point midway between the neck and tail].

For Dogs Weighing 89-132 lbs.

For cartons containing 4.02 ml (0.136 fl. oz.) applicator tube}

Apply one tube (4.02 ml)(0.136 fl. oz.) [as a spot on the dog's back between the shoulder blades]
[from the back of the neck to a point midway between the neck and tail].

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Do not remove tube from the pack until ready to use. Store in a cool [below 77°F (25°C)] dry place inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

PESTICIDE DISPOSAL AND CONTAINER HANDLING: Non-refillable container. Do not reuse or refill this container. **If empty:** Place in trash or offer for recycling if available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

[WARRANTY

Read the entire Directions for Use and Warranty before using this Product. By using this product, user or buyer accepts the following warranty. [[The directions for use of this product are believed to adequate and must be followed carefully. It is impossible to eliminate all risks associated with the use of this product. Unintended consequences may result because of unknown factors. All such risks shall be assumed by the user or buyer.]] Sergeant's is committed to providing high quality products. To the extent consistent with applicable law, Sergeant's makes no warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label. To the extent consistent with applicable law, Sergeant's, the manufacturer, or the Seller shall not be liable for indirect, special, incidental or consequential damages. To the extent consistent with applicable law, the exclusive remedy of the user or buyer shall not exceed the purchase price paid.]

[If you have questions or comments about this product, please write: Sergeant's Consumer Response, P.O. Box 540399, Omaha, NE 68154-0399.]

In Case of Emergency, call: 1-800-781-4738 [For more information] [Visit us at:] [www.sergeants.com]
Non-Emergency call 1-800-224-PETS (7387) [Made in USA]

Sergeant's® Master Label

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Information in [] is optional.

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Distributed by:

Sergeant's Pet Care Products, Inc.

P.O. Box 540399

Omaha, NE 68154-0399

EPA Reg. No. 2517-XX

EPA Est. No. XXXXX-XX-XXX

[BAR CODE AREA]

[Optional Insert or package copy]

[How to Apply - May contain graphics illustrating product use, e.g., dog with a drop falling onto its neck from a vial on front, side, or back carton label and/or applicator labeling.]

[{Outer Packaging or Insert Copy}]

How to open

1. Remove product tubes [vial] from the package.
2. Separate one tube from the others. Holding the tube [vial] with notched end pointing up and away from the face and body, cut off the narrow end at the notches with scissors.

How to apply:

1. Invert tube over dog and use open end to part dog's hair.
2. Squeeze tube firmly to apply all of the solution to the dog's skin [as a spot to the dog's back between the shoulder blades.] [or] [from the back of the neck to a point midway between the neck and tail.]

[Flea life cycle diagram]

[Look at the Label (Look at the Label icon) [Easy] 6 Step [Spot On] [Squeeze-On] [Topical] Checklist

- Read the label completely and follow directions
- Weigh your pet
- Do NOT use Dog products on Cats
- Do NOT treat with more than one pesticide product at a time
- Separate animals after treatment to avoid chance of ingestion
- Do NOT split tubes between pets]

[Brand Name]

[Monthly reminder card]

[Apply [Brand Name] monthly for continuous protection against Fleas (in as little as 1 hour), Ticks (in as little as 1 hour), [and] chewing lice [and mosquitoes].]

[Pet's Name (Empty blank for owner to fill in name)]

[First [dose] [Treatment] (Empty blank for owner to fill in date)]

[Second [dose] [Treatment] (Empty blank for owner to fill in date)]

[Third [dose] [Treatment] (Empty blank for owner to fill in date)]

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[calendar stickers with brand name] [Place stickers on your calendar as a reminder to reapply
[brand name] [in 30 days.]

[Monthly Application Reminder Magnet (image of reminder magnet)

Enclosed for your convenience is an application reminder magnet. Push the (reset) button to start the clock. After 30 days the magnet will flash (and beep) reminding you to reapply [Brand Name]. This application reminder can be used for future treatments. Just press the reset button and in another 30 days the reminder magnet will flash (and beep) reminding you to reapply.]

{END - OPTIONAL INSERT OR PACKAGE COPY}

TUBE / VIAL LABEL

Front Label

{Brand Name}

Fipronil 9.8%, Cyphenothrin 5.0%, (S)-
methoprene 8.8%
0.67 mL (or) 1.34 mL (or) 2.68 mL (or) 4.02
mL {label code}

Back Label

KEEP OUT OF REACH OF CHILDREN

WARNING: Read directions and precautions
before using. Use scissors to open.

EPA REG. No. 2517-XX {label code}

[Optional: Example pictograms that may or may not be found on the printed label]





Sergeant's Pet Care Products, Inc.

2625 South 158th Plaza • Omaha, NE 68130-1770 • Telephone 402.938.7000 • Fax 402.938.7099 • www.sergeants.com

15 December 2009

Richard Gebken
Product Manager 22
Document Processing Desk
Office of Pesticide Programs
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Dear Mr. Gebken:

Sergeant's Pet Care Products, Inc. (Sergeant's, 2625 South 158th Plaza, Omaha, Nebraska 68130-1770, EPA Company Number 2517), authorizes Exponent, Inc. (1150 Connecticut Avenue, NW, Suite 1100, Washington DC, 20036) to act on our behalf, as our Authorized Representative, for all necessary interactions regarding all of our product registration applications and registrations. Please note this does not change the current filed Authorized Agent for Sergeant's.

The Exponent, Inc. contact is as follows:

James Messina and/or Rick Tinsworth
Exponent, Inc.
1150 Connecticut Ave., NW
Suite 1100
Washington, DC 20036
(202) 772-4932
(202) 772-4979 fax
jmessina@exponent.com/rtinsworth@exponent.com

If you have any questions, please contact me at 402-938-7079.

Sincerely,

Kelly R. Hoskins
Manager of Technical Affairs

cc: James Messina

August 11, 2010

Richard Gebken, PM10
Office of Pesticide Programs (7504P) (REGFEE)
U.S. Environmental Protection Agency
Document Processing Desk
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject: Submission of EPA Pesticide Registration Improvement Act Information

Dear Mr. Gebken:

Sergeant's Pet Care Products, Inc. (Sergeant's, 2625 South 158th Plaza, Omaha, NE 68130-1770, EPA Company Number 2517), is submitting Pesticide Registration Improvement Act Information for the following new registration application:

- Sergeant's Fipronil + Cyphenothrin + Methoprene Squeeze-On for Dogs R310, \$4,578 (50% fee waiver \$2,289), Pay.gov Tracking ID: 2510IM08, Agency Tracking ID: 74122352649.

This registration application is for a new end-use product with supporting data and is considered an R310, new end-use product, requires review of data package within RD, PRIA review time frame 6 months, and a fee of \$4,578. Sergeant's qualifies for a PRIA fee waiver/reduction of 50% (refer to OPP Decision Number D-425455).

If you have any questions or need additional information regarding this registration application, please contact me at 402-938-7079.

Sincerely,

Kelly R. Hoskins/zAT

Kelly R. Hoskins
Manager of Technical Affairs

**Voluntary Small Business Certification Form for
Pesticide Registration Fee Waiver/Reduction**

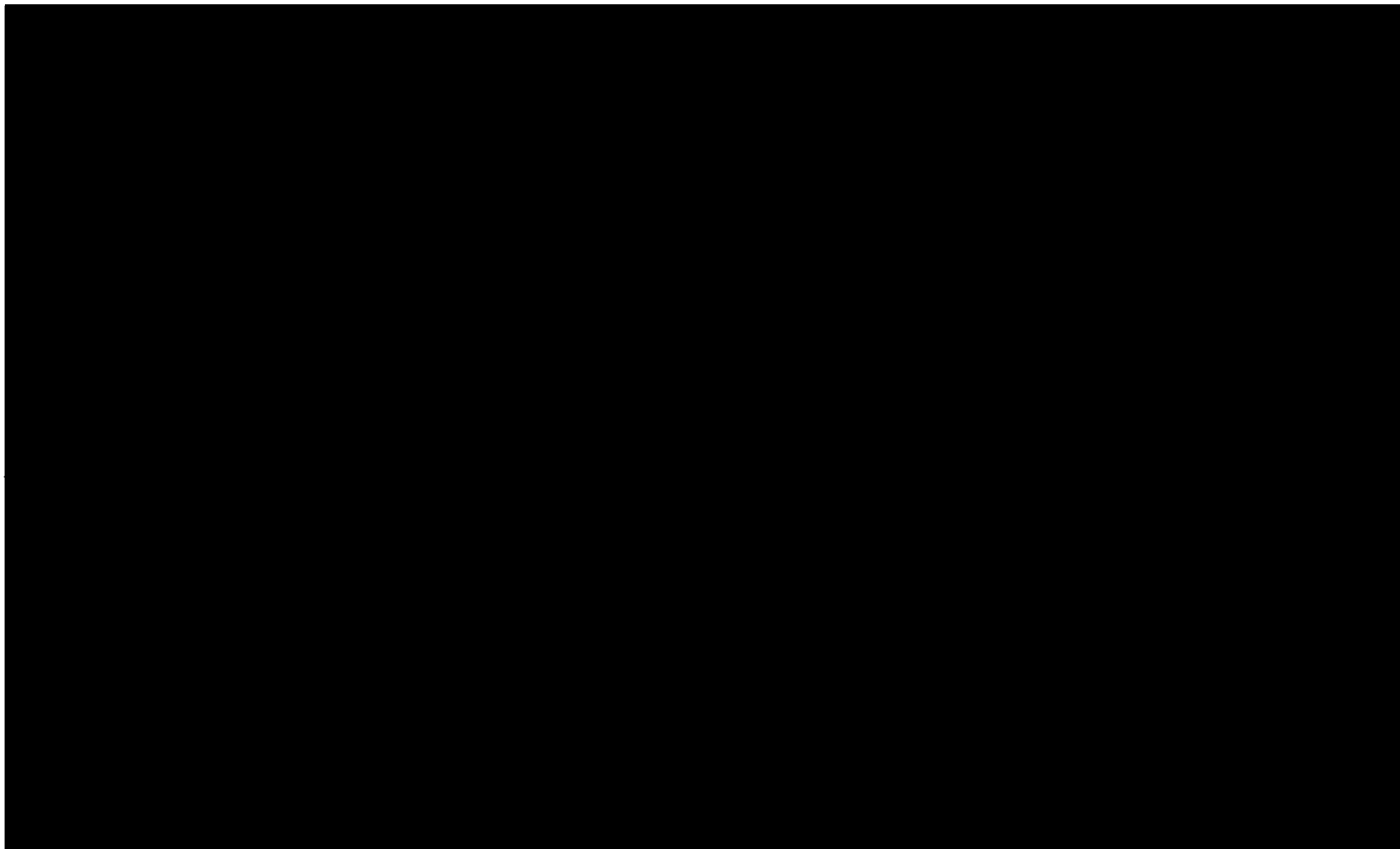
Section 1: Business Identification	
Company Name:	Sergeant's Pet Care Products, Inc.
Address:	2625 South 158 th Plaza Omaha, NE 68130-1770
EPA Company Number:	2517
Contact Name:	Kelly R. Hoskins Manager of Technical Affairs
Phone Number:	402-938-7079
Fax Number:	402-938-7091
Email:	KHoskins@SERGEANTS.com
Section 2: EPA Pending Action Identification	
Product Name:	Sergeant's Fipronil + Cyphenothrin + Methoprene Squeeze-On for Dogs
Description of Action Submitted to EPA:	New end-use product with efficacy data
EPA Identification	2517-NEW
EPA Fee Category and Fee	EPA PRIA fee category R310, 6 month review, \$4,578 (50% fee waiver \$2,289)
Section 3: Small Business Information/Documentation	
Fee Waiver Support as a Small Business (as applicable):	Yes, 50%.
Is the Applicant a business entity with one or more affiliates?	No. Refer to previously filed request of D-425455 (May 4, 2010)
Business structure: include a chart or statement describing the applicant's business entity, its relationships to parent/owner company(s) and/or affiliate company(s), and the percentage interest of each owner/affiliate.	Refer to previously filed request of D-425455 (May 4, 2010)
Including parent and affiliate(s), the applicant's average annual global gross revenue from pesticides for the last 3 years was less than or equal to:	() \$10 million/year (75% fee waiver) (x) \$60 million/year (50% fee waiver)
Documentation: Include revenue statements for the Applicant showing annual global gross revenue from pesticides for each of the three most recent completed fiscal or tax years.	Refer to previously filed request of D-425455 (May 4, 2010)
Applicant's () fiscal year (x) tax year ends on:	September 30
Applicant's Audited Financial Statements are available on/about:	January 31
Does the Applicant now employ 500 or fewer employees?	Yes
Documentation: include the most recent IRS 941 or W3 or other official documentation	Refer to previously filed request of D-425455 (May 4, 2010)

Section 4: Certification Statement

I, Joe Connealy, the Vice President of Finance (title), of the above-named Applicant, am authorized and have personal knowledge sufficient to make this certification on behalf of this Applicant. I hereby certify under penalty of perjury that the information in Sections 1-3 above and the documentation submitted and/or relied on in connection with this Applicant's Fee Waiver/Reduction request are true, complete, and correct in all material respects, and accurately represent the current business status of this Applicant.

Joe Connealy / ZAT 08-11-2010
Joe Connealy Date

Confidential Statement of Formula may be entitled to confidential treatment



Confidential Statement of Formula may be entitled to confidential treatment

